# Table of Contents

Overview .................................................................................................................. 21
A Guide to ISO 13485 - The Quality Management System for Medical Devices .............. 24
A Step-by-Step Approach to Process Validation .................................................................. 24
A Tour of FDA ............................................................................................................... 25
A Tour of Health Canada ................................................................................................. 25
A Tour of Health Europe ................................................................................................. 25
Abandonment of Facilities .............................................................................................. 26
Abnormal Operating Conditions: Recognize and React ...................................................... 26
Abnormal Operations ...................................................................................................... 26
Abnormal Operations and Safety-Related Conditions .......................................................... 26
Access to Employee Exposure and Medical Records .......................................................... 27
Accident Investigation Overview ...................................................................................... 27
Accurate Company Records ............................................................................................. 27
Active Listening Skills ..................................................................................................... 27
Active Shooter: Law Enforcement ...................................................................................... 27
Active Shooter: Prevention and Preparation ....................................................................... 28
Active Shooter: Run, Hide, Fight ..................................................................................... 28
Active Shooter: Victims .................................................................................................... 28
Administrative Roles of the Clinical Research Associate ...................................................... 28
Administrative Roles of the Clinical Research Coordinator ................................................. 28
Aerial Patrol .................................................................................................................... 29
Affirmative Action in the Workplace (For Employers) .......................................................... 29
Age Discrimination .......................................................................................................... 29
Air Permitting Awareness ................................................................................................. 29
Air Permitting for Supervisors .......................................................................................... 30
Americans with Disabilities Act ......................................................................................... 30
An Introduction to ISO 13485 - The Quality Management System for Medical Devices .......... 30
An Introduction to ISO 9001:2015 — The Quality Management System Requirements ............ 30
Antitrust Law and Competitor Relationships ...................................................................... 31
Appeals and Grievances: Classification of Copayment Issues (Micro) ........................................................................ 31
Application of GMPs to Analytical Laboratories .......................................................... 31
Application of GMPs to Microbiology Laboratories ...................................................... 31
Approach to Computerized Systems Validation and Compliance .................................. 32
Asbestos Awareness .................................................................................................... 32
Aspects of Regulatory History .................................................................................... 32
Atmospheric Corrosion - Distribution Operations ......................................................... 32
Atmospheric Corrosion - Pipeline Operations ............................................................. 33
Auditing of Computer System Validation to Ensure Data Integrity ......................... 33
Awareness of FDA Inspections for Pharmaceutical Manufacturers ........................ 33
Backfilling ................................................................................................................... 33
Ball Valve Maintenance ............................................................................................... 34
Basic Corrosion .......................................................................................................... 34
Basic Electronics: PLCs .............................................................................................. 34
Basic Electronics: SCADA .......................................................................................... 34
Basic Radiation Awareness ......................................................................................... 35
Basics of Business Finance ......................................................................................... 35
Basics of Cleanroom Operations ................................................................................ 35
Basics of Inspections: Beginning an Inspection ............................................................. 35
Basics of Inspections: Issues and Observations ........................................................... 36
Basics of PhRMA Code .............................................................................................. 36
Basics of the AdvaMed Code .................................................................................... 36
Batch Record Reviews ................................................................................................ 36
Benzene ....................................................................................................................... 37
Best Practices: Modest Meals ...................................................................................... 37
BIMO: Clinical Investigator .......................................................................................... 37
BIMO: General Inspection Assignment Process ........................................................ 37
BIMO: In Vitro Bioequivalence Program Part I .............................................................. 38
BIMO: In Vivo Bioequivalence Program Part II ............................................................. 38
BIMO: Part 50 & 56 -- Institutional Review Boards (IRBs) ........................................ 38
BIMO: Sponsor/Monitor Responsibilities ................................................................... 38
Biotechnology: An Overview of Compliance Considerations .................................. 39
Bloodborne Pathogens -- General Industry ................................................................. 39
Bloodborne Pathogens – Healthcare Workers ................................................................. 39
Brazil’s Technical Regulations for Medical Devices: RDC 16/2013, 67/2009, and 23/2012 ................................................................. 39
Broker and Agent Training Exam ............................................................................. 40
Building Customer Loyalty ....................................................................................... 40
Business Practices to Protect Personal Health Information ........................................... 40
Canadian Medical Device Regulations ............................................................... 40
Care and Handling of Drug Product Components, Labeling, Containers, and Closures ................................................................. 41
Cast Iron Joints ........................................................................................................ 41
Cathodic Protection - Rectifier Inspections ............................................................ 41
Cathodic Protection Criteria ..................................................................................... 41
Cathodic Protection Troubleshooting ..................................................................... 42
CE Certification for Medical Devices ..................................................................... 42
CFDA Order No. 25 – Good Clinical Practices for Medical Devices ......................... 42
CGIs and Flame Ionization Units ............................................................................ 42
Change Control ........................................................................................................ 43
Characteristics and Properties of Natural Gas ......................................................... 43
Cleanroom Cleaning, Sanitization, and Disinfection ................................................. 43
Clinical Trial Audits and Consequences of Non-Compliance ................................... 43
Close Interval Surveys ................................................................................................ 44
Code of Business Conduct ...................................................................................... 44
Code of Conduct ...................................................................................................... 44
Collecting Samples and Establishing Limits for Cleaning Validation ......................... 44
Combination Products – cGMP Requirements ....................................................... 45
Combustible and Flammable Liquids ...................................................................... 45
Complaint Management for Medical Device Manufacturers ................................... 45
Complaint Management for Pharmaceutical Manufacturers ................................ 45
ComplianceWire Administrator Certification Exam – Advanced ................................ 46
ComplianceWire Administrator Certification Exam – Basic .................................... 46
ComplianceWire Advanced Administrator Certification .......................................... 46
ComplianceWire Basic Administrator Certification ................................................ 46
Compressed Gas ....................................................................................................... 46
Compressor Operation: Compressor Cylinders ....................................................... 46
Compressor Operation: Gas Path Integrity ............................................................ 47
<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compressor Operation: Power Cylinder Balancing</td>
<td>47</td>
</tr>
<tr>
<td>Compressor Operation: Turbine Units</td>
<td>47</td>
</tr>
<tr>
<td>Compressor Station Operations and Safety</td>
<td>47</td>
</tr>
<tr>
<td>Compressor Stations: Design and Emergency Planning</td>
<td>48</td>
</tr>
<tr>
<td>Computer Workstation Safety</td>
<td>48</td>
</tr>
<tr>
<td>Computerized Systems Inspections in the Medical Device Industry</td>
<td>48</td>
</tr>
<tr>
<td>Computerized Systems Inspections in the Pharmaceutical Industry</td>
<td>49</td>
</tr>
<tr>
<td>Conducting Annual Product Reviews</td>
<td>49</td>
</tr>
<tr>
<td>Confidentiality, Intellectual Property Protection, and Information Security</td>
<td>49</td>
</tr>
<tr>
<td>Confined Space Entry</td>
<td>49</td>
</tr>
<tr>
<td>Contractor Safety</td>
<td>50</td>
</tr>
<tr>
<td>Copayment Issue Classification Quiz 1 (Booster #1)</td>
<td>50</td>
</tr>
<tr>
<td>Copayment Issue Classification Quiz 2 (Booster #2)</td>
<td>50</td>
</tr>
<tr>
<td>Copayment Issue Classifying Examples (Booster #3)</td>
<td>50</td>
</tr>
<tr>
<td>Corporate Emergency Management Plan</td>
<td>50</td>
</tr>
<tr>
<td>Corrective and Preventive Actions</td>
<td>51</td>
</tr>
<tr>
<td>Courtroom Testimony</td>
<td>51</td>
</tr>
<tr>
<td>Current Interrupters</td>
<td>51</td>
</tr>
<tr>
<td>Damage Prevention</td>
<td>51</td>
</tr>
<tr>
<td>Data Integrity for Clinical Research Staff</td>
<td>52</td>
</tr>
<tr>
<td>Data Integrity for Quality Control Laboratories</td>
<td>52</td>
</tr>
<tr>
<td>Data Integrity: The Role of Quality Assurance for Data Integrity</td>
<td>52</td>
</tr>
<tr>
<td>Data Privacy Breach Simulation</td>
<td>52</td>
</tr>
<tr>
<td>DEA Compliance</td>
<td>53</td>
</tr>
<tr>
<td>Deficit Reduction Act: False Claims and Employee Protections Training</td>
<td>53</td>
</tr>
<tr>
<td>Dehydration of Natural Gas</td>
<td>53</td>
</tr>
<tr>
<td>Dehydration With Triethylene Glycol</td>
<td>53</td>
</tr>
<tr>
<td>Design Control Regulations for Medical Device Manufacturers</td>
<td>54</td>
</tr>
<tr>
<td>Destruction and Reconditioning</td>
<td>54</td>
</tr>
<tr>
<td>Detecting and Preventing Fraud</td>
<td>54</td>
</tr>
<tr>
<td>Dietary Supplements -- cGMP Requirements for Quality Control</td>
<td>54</td>
</tr>
<tr>
<td>Dietary Supplements -- cGMPs for Manufacturing Plants and Equipment</td>
<td>55</td>
</tr>
<tr>
<td>Dietary Supplements -- Introduction to Part 111 cGMPs</td>
<td>55</td>
</tr>
<tr>
<td>Topic</td>
<td>Page</td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Dietary Supplements -- Packaging, Labeling, Holding, and Distribution</td>
<td>55</td>
</tr>
<tr>
<td>Dietary Supplements -- Production and Process Control System for Manufacturing Operations</td>
<td>55</td>
</tr>
<tr>
<td>Dietary Supplements -- Requirements for Records and Recordkeeping</td>
<td>56</td>
</tr>
<tr>
<td>Discrimination and Harassment Free Workplace</td>
<td>56</td>
</tr>
<tr>
<td>Ditch Witch® Pipe Locators</td>
<td>56</td>
</tr>
<tr>
<td>Diversity in the Workplace</td>
<td>56</td>
</tr>
<tr>
<td>Documenting the Drug Development Process — ICH Q8(R2)</td>
<td>57</td>
</tr>
<tr>
<td>Documenting Validation Activities</td>
<td>57</td>
</tr>
<tr>
<td>Doing Business with the Government</td>
<td>57</td>
</tr>
<tr>
<td>Doing the Right Thing for Customers and Business Partners</td>
<td>57</td>
</tr>
<tr>
<td>Doing the Right Thing: Anti-bribery</td>
<td>58</td>
</tr>
<tr>
<td>Dos and Don’ts of Aseptic Environments</td>
<td>58</td>
</tr>
<tr>
<td>DOT Alcohol Awareness</td>
<td>58</td>
</tr>
<tr>
<td>DOT Drug Awareness</td>
<td>58</td>
</tr>
<tr>
<td>DOT Employee Drug and Alcohol Awareness</td>
<td>59</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- Carrier Requirements (Air)</td>
<td>59</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- Carrier Requirements (Highway)</td>
<td>59</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- Carrier Requirements (Rail)</td>
<td>59</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- General Awareness</td>
<td>60</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- Hazardous Materials Table</td>
<td>60</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- Marking and Labeling</td>
<td>60</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- Packaging</td>
<td>60</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- Placarding</td>
<td>61</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- Security Awareness</td>
<td>61</td>
</tr>
<tr>
<td>DOT Hazardous Materials Training -- Shipping Papers</td>
<td>61</td>
</tr>
<tr>
<td>Dresser Coupled Pipelines</td>
<td>61</td>
</tr>
<tr>
<td>Driver Safety Program (DSP)</td>
<td>62</td>
</tr>
<tr>
<td>Drug Safety &amp; Adverse Event Reporting</td>
<td>62</td>
</tr>
<tr>
<td>Edit Group Criteria Enhancement Overview</td>
<td>62</td>
</tr>
<tr>
<td>Effective Media Relations</td>
<td>62</td>
</tr>
<tr>
<td>Effectively Responding to FDA 483s and Warning Letters</td>
<td>63</td>
</tr>
<tr>
<td>Electric Arc Welding</td>
<td>63</td>
</tr>
<tr>
<td>Electric Valve Actuators</td>
<td>63</td>
</tr>
</tbody>
</table>
Electrical Insulator Inspections and Testing Casings .................................................. 63
Electrical Safety ............................................................................................................... 63
Electrofusion .................................................................................................................... 64
E-Mail and Corporate Communications .......................................................................... 64
Emergency Plans & Public Contractor Education ......................................................... 64
Emergency Preparedness for Healthcare Workers ....................................................... 64
Emergency Response Plan for Natural Gas Pipelines ................................................... 65
Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations .... 65
Environmental Awareness ............................................................................................. 65
Environmental Control and Monitoring ........................................................................ 65
Environmental Management Systems .......................................................................... 66
Environmental Regulation ............................................................................................. 66
EPA Inspections ................................................................................................................ 66
Ergonomics: Body Mechanics and Fitness ...................................................................... 66
Essentials of an Effective Calibration Program ............................................................... 67
Ethical Review Boards .................................................................................................... 67
Ethical Third Party Sales and Marketing Intermediary (“SMI”) Relationships .............. 67
Ethics and Compliance .................................................................................................... 67
Ethics as the Foundation to Clinical Research ............................................................... 68
EU Directives and Inspection Readiness ........................................................................ 68
EU In Vitro Diagnostic Regulations (IVDR) ................................................................. 68
EU Medical Device Regulation (MDR) ........................................................................ 68
European Union Clinical Trials Directive .................................................................... 69
European Union GMP Requirements ............................................................................ 69
European Union GMP Requirements for Computerised Systems ............................... 69
European Union Good Distribution Practices for Medicinal Products ....................... 69
Evidence and Proof .......................................................................................................... 70
Excavations ....................................................................................................................... 70
Facility Response Plan for Hazardous Liquids Pipelines ................................................ 70
Failure Investigations for Medical Device Manufacturers .............................................. 70
Failure Investigations for Pharmaceutical Manufacturers ............................................. 71
Fair Labor Standards Act (FLSA) and Equal Pay Act (EPA) ........................................... 71
Fall Protection .................................................................................................................. 71
<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family and Medical Leave Act (FMLA)</td>
<td>71</td>
</tr>
<tr>
<td>FDA 483s: Inspectors' Observations</td>
<td>72</td>
</tr>
<tr>
<td>FDA Establishment Inspection (EI)</td>
<td>72</td>
</tr>
<tr>
<td>FDA Establishment Inspection Report Writing</td>
<td>72</td>
</tr>
<tr>
<td>FDA Good Guidance Practices (GCPs)</td>
<td>72</td>
</tr>
<tr>
<td>FDA Training and Qualification Requirements</td>
<td>73</td>
</tr>
<tr>
<td>Field Examinations</td>
<td>73</td>
</tr>
<tr>
<td>Financial Disclosure by Clinical Investigators</td>
<td>73</td>
</tr>
<tr>
<td>Fire Extinguishers</td>
<td>73</td>
</tr>
<tr>
<td>Fire Prevention</td>
<td>74</td>
</tr>
<tr>
<td>Fire Safety for Healthcare Workers</td>
<td>74</td>
</tr>
<tr>
<td>First Aid</td>
<td>74</td>
</tr>
<tr>
<td>Flammable and Combustible Liquids</td>
<td>74</td>
</tr>
<tr>
<td>Food and Drug Law: Criminal Acts Violations</td>
<td>75</td>
</tr>
<tr>
<td>Food and Drug Law: FDA Jurisdictions</td>
<td>75</td>
</tr>
<tr>
<td>Food and Drug Law: Imports and Exports</td>
<td>75</td>
</tr>
<tr>
<td>Food and Drug Law: Judicial Actions</td>
<td>76</td>
</tr>
<tr>
<td>Food and Drug Law: Prohibited Actions</td>
<td>76</td>
</tr>
<tr>
<td>Foreign Corrupt Practices Act (FCPA)</td>
<td>76</td>
</tr>
<tr>
<td>Forklift Safety</td>
<td>76</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>77</td>
</tr>
<tr>
<td>Fraud and Abuse Awareness</td>
<td>77</td>
</tr>
<tr>
<td>Fundamentals of Electricity</td>
<td>77</td>
</tr>
<tr>
<td>Gas Control</td>
<td>77</td>
</tr>
<tr>
<td>Gate Valve Maintenance</td>
<td>78</td>
</tr>
<tr>
<td>GCP/ICH Obligations of Sponsors and Monitors</td>
<td>78</td>
</tr>
<tr>
<td>GCP/ICH Obligations of Sponsors, Monitors, and Investigators</td>
<td>78</td>
</tr>
<tr>
<td>General Data Protection Regulation</td>
<td>78</td>
</tr>
<tr>
<td>General Overview and Philosophy of IEC 60601</td>
<td>79</td>
</tr>
<tr>
<td>General Valve Maintenance</td>
<td>79</td>
</tr>
<tr>
<td>Global Anti-Bribery</td>
<td>79</td>
</tr>
<tr>
<td>Global Anti-Bribery: UK</td>
<td>79</td>
</tr>
<tr>
<td>Global Fair Competition Laws</td>
<td>79</td>
</tr>
</tbody>
</table>
Global Regulatory Strategy and Planning Process .......................................................... 80
Glutaraldehyde .................................................................................................................. 80
GMP Principles for Batch Records .................................................................................. 80
GMP Principles of SOPs .................................................................................................. 80
GMP Updates: Supply Chain Quality and Emerging Compliance Concerns .................. 81
Good Clinical Practices (GCPs) for New Product Investigations .................................. 81
Good Documentation Practices for Medical Device Manufacturers ............................... 81
Good Laboratory Practices (GLPs) .................................................................................. 81
Gowning for Sterile Manufacturing ................................................................................ 82
Guidelines for Proctoring Tests and Evaluations ............................................................ 82
Guidelines of Workplace Safety ..................................................................................... 82
GxPs ................................................................................................................................. 83
Handling a Product Recall ............................................................................................... 83
Handling an FDA Inspection ........................................................................................... 83
Handling Confidential Information ................................................................................. 83
Harassment Avoidance Training for California ............................................................... 84
Harassment in the Workplace .......................................................................................... 84
Hazard Communication .................................................................................................. 84
Hazard Communication - Safety Data Sheets (US) ......................................................... 84
Hazardous Waste Determination .................................................................................... 85
Hazardous Waste Disposal ............................................................................................. 85
Hazardous Waste Drum Management ............................................................................. 85
HAZWOPER Awareness ................................................................................................. 85
HAZWOPER Refresher Training - Module 7 - Respiratory Protection (US) ..................... 86
HAZWOPER Refresher Training - Module 8 - Personal Protective Equipment (PPE) (US) 86
Hearing Conservation ..................................................................................................... 86
Heat Stress ......................................................................................................................... 86
High Purity Water Systems .............................................................................................. 87
HIPAA -- The Impact On Clinical Research ................................................................... 87
HIPAA and Privacy Guidelines for Medical Device Sales Representatives ................... 87
HIPAA and Privacy Guidelines for Pharmaceutical Sales Representatives .................. 87
HIPAA Privacy: Role-Based Training I (Incidental PHI Contact) ................................... 88
HIPAA Privacy: Role-Based Training II (Internal Uses of PHI) ..................................... 88
HIPAA Privacy: Role-Based Training III (Uses and Disclosures of PHI) ..................................................... 88
HIPAA Privacy: Role-Based Training IV (Managers, Supervisors, and Compliance Staff) ........................................ 88
HIPAA: General Awareness ......................................................................................................................... 89
HIPAA: Privacy Standards .......................................................................................................................... 89
Hiring and Firing ........................................................................................................................................ 89
Hoists and Rigging ..................................................................................................................................... 90
Hot Tapping ............................................................................................................................................. 90
Hot Work Permits .................................................................................................................................... 90
How to Build a UL CREATE Course ........................................................................................................ 90
How to Edit a UL CREATE Course ........................................................................................................... 91
How to Meet Drug Retention and Stability Testing Requirements .......................................................... 91
HP: Compliance Program General Session ............................................................................................... 91
Human Performance Systems ..................................................................................................................... 91
Hydrogen Sulfide (H2S) ............................................................................................................................. 92
ICH QCP Obligations of Investigators Conducting Clinical Trials ............................................................. 92
ICH Q7: Resources and Materials Management ....................................................................................... 92
ICH Q7A: Introduction and Quality Management ..................................................................................... 92
IEC 61010 — Measurement, Control, and Laboratory Use Equipment .................................................... 93
IEC 61010-1: Measurement, Control, and Laboratory Use Equipment — Standards and Application ............ 93
IEC 62304: Medical Device Software Development Process and Risk Management .................................... 93
IEC 62304: Medical Device Software Life Cycle Processes and Requirements ........................................... 93
Implementing an Equipment Qualification Program .................................................................................. 94
Import Operations 1: Background ............................................................................................................... 94
Import Operations 2: The Process ............................................................................................................... 94
Import Operations 3: Other Activities ........................................................................................................ 94
Improving Productivity ............................................................................................................................... 95
Incident Command System and Natural Gas Emergencies ...................................................................... 95
Infection Prevention and Control .............................................................................................................. 95
Information Security ................................................................................................................................. 95
Informed Consent ..................................................................................................................................... 96
Inspecting and Testing Control Valves ........................................................................................................ 96
Inspecting and Testing Pressure Limiting Devices .................................................................................... 96
Inspecting and Testing Regulators ........................................................................................................... 96
Install Meters and Regulators - Commercial ................................................................. 97
Install Meters and Regulators - Residential ................................................................. 97
Installation of Anodes ................................................................................................. 97
Installation of Plastic Mains and Services - Part 1 ....................................................... 97
Installation of Plastic Mains and Services - Part 2 ....................................................... 98
Installation of Steel Mains and Services .................................................................... 98
Installation of Test Stations ....................................................................................... 98
Interactions with Healthcare Professionals - Field ....................................................... 98
Interactions with Healthcare Professionals - In-House ............................................... 99
Interference: AC and DC .......................................................................................... 99
Internal Corrosion ..................................................................................................... 99
Interviewing Techniques ........................................................................................... 99
Introduction to CFDA and CFDA Registration .............................................................. 100
Introduction to Data Integrity .................................................................................... 100
Introduction to GMPs ............................................................................................... 100
Introduction to Medicaid .......................................................................................... 100
Introduction to Medical Device Health Care Compliance ......................................... 101
Introduction to Pharmaceutical Compliance .............................................................. 101
Introduction to Risk Management ........................................................................... 101
Introduction to Specialty Pharmacy Management ...................................................... 101
Introduction to the Medical Device Single Audit Program (MDSAP) ....................... 102
Introduction to the Natural Gas Industry .................................................................. 102
Introduction to the Quality System Regulation (QSR) ............................................... 102
Introduction to the Regulation of Prescription Drug and Biologic Promotions ........... 102
Introduction to Waste Management and Minimization .............................................. 103
Investigating Pipeline Failure ................................................................................... 103
Investigational Product Development .................................................................... 103
ISO 14155: Obligations of Sponsors and Monitors for Medical Device Trials ........... 103
ISO 14971: Risk Management for Medical Devices ................................................ 104
Isolators for Aseptic Processing ............................................................................... 104
Japanese Medical Device and Pharmaceutical Regulations ..................................... 104
Job Performance Evaluations .................................................................................. 104
Joining Steel Pipe Other Than by Welding ............................................................... 105
Key Concepts of Process Validation ................................................................. 105
Laboratory Safety ......................................................................................... 105
Laboratory Specimens for Clinical Research .................................................. 105
Ladder Safety ................................................................................................. 106
Lead ............................................................................................................... 106
Leak & Pipeline Failure Investigation .............................................................. 106
Leak Survey & Leak Classification ................................................................. 106
Lean Six Sigma Case Study ............................................................................ 106
Lean Six Sigma Leadership and Improvement Teams ...................................... 107
Lean Six Sigma Overview .............................................................................. 107
Lean Six Sigma Principles and Core Methodologies ....................................... 107
Line Stopping .................................................................................................. 107
Locating and Marking Buried Pipelines .......................................................... 107
Lockout/Tagout – Affected .............................................................................. 108
Lockout/Tagout – Authorized .......................................................................... 108
LQ: Abnormal Operations .............................................................................. 108
LQ: Aboveground Storage Tank Overfill Protection ....................................... 108
LQ: Below Ground Pipe Coatings & Exposed Pipe ....................................... 109
LQ: Cathodic Protection - Aboveground Storage Tanks .................................... 109
LQ: Cathodic Protection Troubleshooting ....................................................... 109
LQ: Conduct Annual Surveys ......................................................................... 109
LQ: Flushing and Purging Pipeline Systems ..................................................... 110
LQ: Inspecting and Testing Control Valves ....................................................... 110
LQ: Inspection - Aboveground Storage Tanks ................................................ 110
LQ: Installation of Anodes .............................................................................. 110
LQ: Installation of Test Stations ...................................................................... 111
LQ: Interference (AC and DC) ........................................................................ 111
LQ: Introduction to Compressor and Pump Operations ..................................... 111
LQ: Marking Pipelines - Temporary and Permanent ........................................ 111
LQ: Meter Maintenance and Proving ............................................................... 112
LQ: Pigging: Launching and Receiving .......................................................... 112
LQ: Pipeline Patrol ......................................................................................... 112
LQ: Pipeline System Control ......................................................................... 112
<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obligations of Investigators in Conducting Medical Device Trials</td>
<td>129</td>
</tr>
<tr>
<td>Odorization: Concentration Testing</td>
<td>130</td>
</tr>
<tr>
<td>Office Safety</td>
<td>130</td>
</tr>
<tr>
<td>OIG Compliance Program/Guidance for Medical Device Manufacturers -- Field Force</td>
<td>130</td>
</tr>
<tr>
<td>Operating Room Conduct</td>
<td>130</td>
</tr>
<tr>
<td>Operator Qualification Summary</td>
<td>131</td>
</tr>
<tr>
<td>Orientation to GMP Compliance</td>
<td>131</td>
</tr>
<tr>
<td>OSHA/DOT - Excavation Safety</td>
<td>131</td>
</tr>
<tr>
<td>Overcoming Negativity in the Workplace</td>
<td>131</td>
</tr>
<tr>
<td>Overview of FDA's Bioresearch Monitoring Program</td>
<td>132</td>
</tr>
<tr>
<td>Overview of the Clinical Research Process</td>
<td>132</td>
</tr>
<tr>
<td>Overview of the Preparation Requirements for the ICH Common Technical Document</td>
<td>132</td>
</tr>
<tr>
<td>Oxygen/Acetylene Welding &amp; Cutting</td>
<td>132</td>
</tr>
<tr>
<td>Packaging and Labeling of Finished Pharmaceuticals</td>
<td>133</td>
</tr>
<tr>
<td>Pandemic Preparedness: What Every Employee Should Know</td>
<td>133</td>
</tr>
<tr>
<td>Part 11: Electronic Records and Signatures -- Application</td>
<td>133</td>
</tr>
<tr>
<td>Part 11: Electronic Records and Signatures -- Changes in Enforcement Policy</td>
<td>133</td>
</tr>
<tr>
<td>Part 11: Electronic Records; Electronic Signatures</td>
<td>134</td>
</tr>
<tr>
<td>Personal Leadership Power</td>
<td>134</td>
</tr>
<tr>
<td>Personal Protective Equipment</td>
<td>134</td>
</tr>
<tr>
<td>Pharmaceutical and Medical Device Supplier Quality Management</td>
<td>134</td>
</tr>
<tr>
<td>Pharmaceutical Risk Management: Picking the Right CAPA Tools</td>
<td>135</td>
</tr>
<tr>
<td>Photography for FDA Enforcement</td>
<td>135</td>
</tr>
<tr>
<td>Physical and Network Security</td>
<td>135</td>
</tr>
<tr>
<td>Physician Payment Sunshine Act</td>
<td>135</td>
</tr>
<tr>
<td>Pipeline Crossings</td>
<td>136</td>
</tr>
<tr>
<td>Pipeline Integrity: High Consequence Area Field Surveys</td>
<td>136</td>
</tr>
<tr>
<td>Pipeline Pigging</td>
<td>136</td>
</tr>
<tr>
<td>Pipeline Purging With Air and Gas</td>
<td>136</td>
</tr>
<tr>
<td>Pipeline Repair: Composites</td>
<td>136</td>
</tr>
<tr>
<td>Pipeline Repair: Grinding, Welding, and Sleeving</td>
<td>137</td>
</tr>
<tr>
<td>Pipeline Repair: Sleeving Including Helical Pipe</td>
<td>137</td>
</tr>
<tr>
<td>Pipeline Security Planning</td>
<td>137</td>
</tr>
</tbody>
</table>
Pipeline Shutdown and Startup Planning .............................................................. 137
Pipeline Tie-in Methods .................................................................................. 137
Plastic Pipe Fusion .......................................................................................... 138
Plug Valve Maintenance .................................................................................. 138
Population Density Change & Pipeline Patrol .................................................. 138
Postmarketing Reporting of Adverse Drug Experiences ................................... 138
PPE Assessment .............................................................................................. 139
Pre- and Post-Approval FDA Drug Inspections .................................................. 139
Pressure Testing Plastic Pipelines ..................................................................... 139
Pressure Testing Steel Pipelines - Gas ............................................................... 139
Preventing Back Injuries .................................................................................. 140
Preventing Sexual Harassment ........................................................................ 140
Prevention of Accidental Ignition & Potential Ignition Sources ....................... 140
Principles of Aseptic Processing ....................................................................... 140
Principles of Auditing ...................................................................................... 141
Principles of Cleaning Validation ..................................................................... 141
Principles of Good Documentation ................................................................... 141
Principles of Restricted Access Barrier Systems and Isolators ......................... 141
Principles of Sterilization .................................................................................. 142
Privacy and Data Protection ............................................................................. 142
Process Gaue Radiation .................................................................................... 142
Process Safety Management: Compliance Audits .............................................. 142
Process Safety Management: Contractors ....................................................... 143
Process Safety Management: Incident Investigation ......................................... 143
Process Safety Management: Management of Change ....................................... 143
Process Safety Management: Mechanical Integrity .......................................... 144
Process Safety Management: Operating Procedures ........................................ 144
Process Safety Management: Overview ........................................................... 144
Process Safety Management: Pre-Startup Safety Review .................................. 144
Process Safety Management: Process Hazard Analysis ..................................... 145
Process Safety Management: Process Safety Information ............................... 145
Process Safety Management: Training ............................................................. 145
Promotion of Pharmaceutical Products – Field Facing ...................................... 145
Promotion of Pharmaceutical Products -- In House .......................................................... 146
Protection of Human Subjects in Clinical Trials ............................................................... 146
Protective Coatings .......................................................................................................... 146
Public Awareness ............................................................................................................. 147
Q10 Pharmaceutical Quality System ................................................................................ 147
Q9: Quality Risk Management .......................................................................................... 147
QS Regulation 1: Overview and General Provisions ......................................................... 147
QS Regulation 10: Servicing; Statistical Techniques ......................................................... 148
QS Regulation 11: Application and Inspection of QS Regulation Requirements .............. 148
QS Regulation 2: Quality System Requirements ............................................................... 148
QS Regulation 3: Design Controls .................................................................................... 149
QS Regulation 4: Document and Purchasing Controls ..................................................... 149
QS Regulation 5: Identification and Traceability; Production and Process Controls ....... 149
QS Regulation 6: Acceptance Activities; Nonconforming Product ................................ 150
QS Regulation 7: Corrective and Preventive Action .......................................................... 150
QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution, and Installation .......................................................... 150
QS Regulation 9: Records ................................................................................................. 151
QSIT 1 -- Beginning the Inspection .................................................................................. 151
QSIT 2 -- The Management Controls Subsystem ............................................................ 151
QSIT 3 -- The Design Controls Subsystem ..................................................................... 151
QSIT 4 -- The Corrective and Preventive Actions Subsystem ........................................ 152
QSIT 5 -- The Production and Process Controls Subsystem .......................................... 152
Quality Management Refresher ...................................................................................... 152
Quality Systems Approach .............................................................................................. 152
Quality Systems Inspection Technique (QSIT) ............................................................... 153
RABS for Aseptic Processing ............................................................................................ 153
Recalls of FDA Regulated Products ................................................................................ 153
Reciprocating Compressor Units ..................................................................................... 153
Recognizing and Avoiding Conflicts of Interest ............................................................. 154
Recognizing and Avoiding Insider Trading ..................................................................... 154
Recruitment and Retention of Study Patients .................................................................. 154
Regulatory Requirements for Medical Devices in the Republic of Korea .................... 154
Reporting Adverse Events for Medical Devices ............................................................... 155
Requirements for Computerized Systems Validation and Compliance ............................................. 155
Resolving Out Of Specification Test Results ................................................................................. 155
Respiratory Protection .................................................................................................................. 155
Respiratory Protection Awareness (US) ......................................................................................... 156
Review of Basic Statistical Techniques ....................................................................................... 156
Rigging: Planning and Inspections ............................................................................................... 156
Right-of-Way Agent Training: Landowner Communications ...................................................... 156
Risk Management 1: Key Concepts and Definitions ................................................................. 157
Risk Management in Pharmaceutical Manufacturing ............................................................... 157
Role of IEC 60601 Around the World ......................................................................................... 157
Role of the Qualified Person ....................................................................................................... 157
Safe Driving ............................................................................................................................... 157
Safe Rigging Practices ................................................................................................................ 158
Safeguarding Intellectual Property ............................................................................................. 158
Safety Signs and Color Codes ..................................................................................................... 158
Sample Collection ...................................................................................................................... 158
Sarbanes-Oxley Act: An Overview ............................................................................................. 159
Scaffold Safety ............................................................................................................................ 159
Scope of Standard and Equipment Classification ........................................................................ 159
Section 1557 of the Affordable Care Act .................................................................................. 159
Security Measures for Employees ............................................................................................... 159
Selecting and Managing Clinical Contract Research Organizations (CROs) ................................ 160
Self-Motivation ............................................................................................................................ 160
Sexual Harassment Awareness for Employees .......................................................................... 160
Sexual Harassment Awareness for Managers ......................................................................... 161
Sexual Harassment Awareness for New York Employees and Supervisors ................................ 161
Sexual Harassment Policy .......................................................................................................... 161
SMART Goal Setting .................................................................................................................. 162
SPCC Plans for Non-Production/Bulk Storage Facilities .......................................................... 162
SPCC Plans for Onshore Production Facilities .......................................................................... 162
Special Investigations ................................................................................................................ 162
Special Needs Plans: Model of Care ......................................................................................... 163
Sterile Dosage Forms Introduction ............................................................................................ 163
Structure of IEC 60601 ................................................................. 163
Structure-to-Electrolyte Surveys ............................................... 163
Substance Abuse .................................................................... 164
System Control: Control Room Management Regulations .......... 164
System Control: Fatigue Management for Controllers ............... 164
System Control: Fatigue Management for Supervisors .......... 164
Systems Based Drug Inspections .............................................. 165
Testing for Bacterial Endotoxins .............................................. 165
The Approval Process for New Medical Devices ...................... 165
The Clinical Development Process: Investigational Product, Plan, and Data Management ........................................ 165
The Design and Development of Software Used in Automated Process Controls .................................................. 166
The Mentoring Process .............................................................. 166
The Role of the Clinical Research Associate ............................. 166
The Role of the Clinical Research Coordinator ......................... 166
Tool Safety .............................................................................. 167
Toxic Substance Control Act (TSCA) Reporting ....................... 167
Trade Secrets ......................................................................... 167
Tuberculosis: Exposure Prevention and Control ......................... 167
U.S. Trade Controls ................................................................. 167
Ultrasonic Thickness Testing .................................................... 168
Underground Storage of Natural Gas and Liquids .................... 168
Understanding GMPs for Facilities and Equipment .................. 168
Understanding Post-Approval Changes ..................................... 168
Understanding the Principles and Practices of Process Controls .... 169
Uniform Hazardous Waste Manifest Completion .................... 169
Up-Rating Pipeline Systems ..................................................... 169
Using a Digital Multimeter ....................................................... 169
Using the DTEX® Odorant Detection Instrument ...................... 170
Using the Heath Gasurveyor® 3-500 ......................................... 170
Using the Heath ODORATOR® .................................................. 170
Using the Metrotech Pipe Locator ............................................ 170
Using the Radiodetection Pipe Locator ..................................... 170
Using the T82 Single Gas Monitor ............................................ 171
Overview

UL PURE™ Learning has partnered with corporate and government clients in the Life Science, Health Care, Energy and General Industry markets for over 30 years.

We currently maintain more than 500 eLearning courses that are written and reviewed by recognized subject matter experts, including the US FDA. In fact, more than 1 million industry professionals, including over 36,000 FDA investigators, have completed over seven million courses since 2003.

Courses are regularly updated to reflect the most current expectations and requirements of regulators and industry groups. Our global quality and compliance management methodology has resulted in measurable performance and compliance improvements. Our eLearning philosophy is based on Mastery Learning, which has been proven to improve retention and change behavior in adult learners through methods that include interaction with dynamic content and built-in assessments.

Should your organization have unique training requirements, you can rely on our Content Solutions team, which develops about 4,000 courses each year for our clients. Our team shares best practices as it relates to instructional design and multi-media, such as incorporating your organization’s unique content and branding into our standard courses.

Many courses are mobile-ready and can be translated into 34 languages. Courses can be hosted independently on your own LMS, or take advantage of UL’s industry standard LMS for Life Science organizations – ComplianceWire®. Learn more about UL PURE Learning’s courses and additional solutions at ulpurelearning.com.

Medical Device - Sales & Marketing
This library, specifically targeted to the Medical Device industry, helps to meet the needs of regulatory, legal, communications, compliance and other Medical Device professionals who engage in marketing, advertising, promotional and communications activities. Incorporating these courses into your vendor credentialing, or Health Care Industry Representative HCIR programs, helps to ensure that sales representatives have the proper training to enter health care facilities.

Clinical: Medical Device
This library, specifically targeted to the Medical Device industry covers underlying Good Clinical Practice (GCP) concepts as well as specific, advanced information for clinical professionals based on their role in the study. The courses are designed for those in clinical development, clinical operations, quality management and regulatory affairs. The global curriculum includes courses describing FDA regulations, ISO 14155, EU directives and ICH guidance; many courses feature content provided by the FDA.

Clinical: Pharmaceutical
The Clinical Pharmaceutical library focuses on the underlying Good Clinical Practice (GCP) concepts as well as specific, advanced information for Pharmaceutical clinical professionals based on their role in the study. The courses are designed for those in clinical development, clinical operations, quality management and regulatory affairs. The global curriculum includes courses describing FDA regulations, ISO 14155, EU directives and ICH guidance; many courses feature content provided by the FDA.

FDA BIMO Course Series
The FDA's BIMO (Bioresearch Monitoring) online training program is designed for FDA Investigators, Supervisors, Compliance Officers and Chief Science Officers (CSOs) from other Centers who have limited experience in the BIMO program and who will conduct inspections or review Establishment Inspection Reports (EIRs) of Clinical Investigators (CIs), Institutional Review Boards (IRBs), Sponsors, Monitors, Contract Research Organizations (CROs) and in vivo Bioequivalence inspections. Using this BIMO training program, clinical professionals can become more familiar with the FDA’s expectations and prepare accordingly.

Data Integrity
Since 2014, US FDA and EMA pharmaceutical/medicine GxP enforcement trends have pointed to a concentrated focus on a lack of data integrity. Investigators have cited manufacturers with a number of data integrity observations, such as failing to document GxP activities at the “time of performance”, and failing to have appropriate controls over computer systems to assure only authorized personnel can change GxP records. Both US FDA and EU expect companies to have valid data, spanning all GxP functions: labs, clinical trials, and the manufacturing process. Ensuring data integrity requires a combination of proper quality systems, but also the proper quality culture. UL’s Data Integrity program includes several eLearning courses that present real-world case studies on how all employees can raise the culture of quality through the recording of GxP activities. Courses include modules targeted to specific roles, such as QA, Clinical, IT and Lab professionals. In addition, an introductory course can be delivered to all GxP employees. Using this program, companies can not only demonstrate to auditors that GxP personnel are aware of the importance of data integrity issues, they can also raise the overall quality culture of their organization, which leads to greater accuracy of clinical, lab and manufacturing records.

Medical Device GMPs
This library focuses on foundational GMP topics as well as the specialized knowledge needs of individual business functions in Pharmaceutical and Biotechnology companies. Beginning with the core quality and regulatory knowledge typically needed by new hires and reassigned workers, to the more advanced needs of managers and supervisors, courses target the function-specific needs of the entire organization. Many of these courses have been reviewed by the FDA and AdvaMed, the leading advocacy group for Medical Device organizations.

FDA Inspections and Enforcement
UL PURE Learning maintains a unique partnership with the FDA, collaborating to develop courses for the FDA's Investigator training program, which has been
UL Pure Learning's Engineering Safety Library focuses on the critical ISO and IEC standards that impact the development and approval of medical device management.

Medicare Part D

The Medicare Advantage curriculum fulfills CMS regulatory requirements for MA organization training, education and documentation. The Library focuses on topics such as enrollment, disenrollment, claims, marketing, quality management, administration and management, utilization management, bids, benefits and provider issues. Our internal regulatory compliance attorneys and our nationally-recognized Medicare Advantage subject-matter experts have developed this curriculum that not only fulfills the training requirements, but is also regularly updated to reflect changes in regulations and CMS sub-regulatory guidance. The breadth of our MA Library not only facilitates compliance with CMS regulations, but also provides in-depth training that ensures your employees perform their department-specific functions successfully.

Medicare Part D

Our Medicare Part D Curriculum expressly created for the Managed Care industry is the most comprehensive and detailed curriculum available and fulfills the CMS requirements for training, education and documentation in a cost-effective training method as outlined in Chapter 9 - Part D Program to Control Fraud, Waste and Abuse of the Prescription Drug Benefit Manual. Our curriculum consists of courses on topics such as fraud and abuse, administration and management, appeals and grievances, bid submission, claim and payment processes, enrollment, disenrollment, marketing, pharmacy access and quality management.

Engineering Safety

UL Pure Learning’s Engineering Safety Library focuses on the critical ISO and IEC standards that impact the development and approval of medical device products. These standards include IEC 60601, ISO 14971 and others. The library serves to introduce these standards to compliance engineers, product safety engineers, and product designers within medical device and medical technology companies. Clients can combine these eLearning courses with optional, face-
to-face workshops that are conducted by UL consultants.

**Medicare Broker/Agent Training**
UL’s five-course training program plus exam for Medicare brokers and agents complies with all Center for Medicare and Medicaid Services (CMS) requirements (excluding plan-specific information) and incorporates the instructional design and knowledge that have made our other Health Care courses so effective. UL has worked with health plans and service providers to address the intersecting challenges of member services and education, regulatory compliance and workforce productivity, resulting in industry-specific solutions for companies that serve the public through group or individual plans, Medicare-eligible enrollees, or individuals who receive government-sponsored coverage.

**RETIRED - Energy Operations**
UL partners with companies in the Energy, Petroleum and Natural Gas industries to address the challenges of on-site safety, cross-functional staff utilization, subcontractor performance and the escalating scrutiny of regulatory agencies. Our combined technologies, services and training curricula support corporate goals for compliance with applicable federal and state requirements, skills training, risk management and efficient operations.

**PPACA**
To help your employees understand the impact of PPACA, UL PURE Learning has developed these three eLearning courses. These courses focus on the changing U.S. Health Care system wrought by the Affordable Care Act and the options that individuals will have to purchase health insurance.
A Guide to ISO 13485 - The Quality Management System for Medical Devices

This course serves as a guide to ISO 13485 — the international quality management system standard for medical devices. The requirements of the standard apply to the methods used in, and the facilities and controls used for, the design and development, production, installation, and servicing of medical devices. Topics in this course include: Quality Management System, Management's Role, Managing Resources, Planning, Design and Purchasing, Production, Monitoring and Analysis, and Improvement. This course also addresses specific aspects of ISO 13485 as it relates to the European Union (EU). After completing this course, learners will be able to recognize the specific requirements of ISO 13485 and apply them to specific situations.


Languages Available:
- German (DEV50)
- French (European) (DEV50)
- Spanish (Latin America) (DEV50)
- Chinese (Simplified) (DEV50)
- Japanese (DEV50)
- Korean (DEV50)


This course serves as a guide to ISO 9001:2015 — the international quality management system requirements standard. This standard specifies requirements to demonstrate an organization's ability to consistently provide products and services that meet customer satisfaction and applicable statutory and regulatory requirements. Topics in this course include: System and Process, Leadership, Planning, Support, Operation, Performance Evaluation, and Improvement. After completing this course, learners will be able to recognize the specific requirements of ISO 9001:2015 and identify management's role in implementation and maintenance of the standard. Learners will also be able to recognize the requirements for quality management system Clauses 4–10 and recognize how to ensure compliance with the standard.

Format: eLearning - EduFlex, eLearning - SCORM

Languages Available:
- Chinese (Simplified)
- German
- Korean
- Spanish (Spain)

A Step-by-Step Approach to Process Validation

Process validation is required by process control regulations for both drugs and medical devices. This course outlines the important tasks performed during each phase of the validation life cycle, as well as the information that should (and should not) be included in validation documents and why processes must be monitored once they are validated. Topics in this course include: Validation Life Cycle, Process Design, Process Qualification including IQ, OQ, PQ, Product Process Qualification, Change Control, and Documentation. After completing this course, you will be able to recognize the validation life cycle, process validation steps, and how the EU regulations differ from FDA requirements. You will also be able to identify validation principles that pertain to the medical device industry.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Languages Available:
- German (PHDV79)
- French (European) (PHDV79)
- Chinese (Simplified) (PHDV79)
- Japanese (PHDV79)
- Korean (PHDV79)
- Spanish (Spain) (PHDV79)
A Tour of FDA

The Food and Drug Administration (FDA) touches the lives of virtually every American, every day. This course outlines the form and function of the FDA, its upper level structure, and its mission and goals. Topics in this course include: History and Scope of FDA, FDA Organization, Program Centers, Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Veterinary Medicine, National Center for Toxicological Research, and Center for Tobacco Products.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Languages Available: Chinese (Simplified) (PHDV60), Japanese (PHDV60), Portuguese (Brazil) (PHDV60)

Partners: FDA

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- FDA Inspection Readiness

A Tour of Health Canada

Health Canada touches the lives of virtually every Canadian, every day. This course introduces participants to Health Canada’s mission and organization. After a brief introduction, the course will focus on the Health Products and Food Branch (HPFB) of Health Canada, which directly affects pharmaceutical manufacturers. Topics in this course include: Purpose, Organization, HPFB, TPD, BGTD, and HPFBI. After completing this course, learners will be able to identify the major branches of Health Canada, the HPFB, and its directorates. Learners will also be able to identify the unique roles and responsibilities of the three HPFB directorates that most directly affect the pharmaceutical industry.

Format: eLearning - SCORM, eLearning - EduFlex

Languages Available: French (Canadian)

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- Canada Regulations

A Tour of Health Europe

The system in Europe for ensuring safe, effective, and high-quality health products is composed of national authorities in individual countries as well as bodies in the European Union and the Council of Europe. After completing this course, learners will know the organisations that oversee the health industry in Europe and the bodies in those organisations that affect pharmaceutical companies. Learners will also understand how health products can be approved for sale to the public and the system for reporting and tracking defective products.

Format: eLearning - HiP2

Languages Available: Chinese (Simplified) (PHDV90), Japanese (PHDV90), Portuguese (Brazil) (PHDV90)

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical
- Global Regulatory

Functional Areas:
- EU Regulations
Abandonment of Facilities

Abandonment of Facilities examines deactivation and abandonment of steel and plastic pipeline facilities including mains, services, regulators, meters, and odorizers; and the importance of documenting deactivated and abandoned facilities.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Abnormal Operating Conditions: Recognize and React

Abnormal Operating Conditions: Recognize and React covers the definition of abnormal operating conditions (AOCs), identifying AOCs, operator qualification, identification of covered tasks, recognition and reaction to AOCs, and rating hazards. This course assists in compliance with DOT regulations and references the B31J standard.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Abnormal Operations

Abnormal Operations explores the difference between abnormal operations and abnormal operating conditions (AOCs). The course also examines how to respond to, report, and record abnormal operations.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Abnormal Operations and Safety-Related Conditions

Abnormal Operations and Safety-Related Conditions explains the difference between abnormal operations and abnormal operating conditions, describes safety-related conditions, and explains how to recognize possible causes of abnormal operations including appropriate responsive actions. Reporting requirements for safety-related conditions are also stated. References to DOT standards that apply to abnormal operations and safety-related conditions are listed.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics
Access to Employee Exposure and Medical Records

Employers must keep medical or exposure records for all employees who have been exposed to a hazardous substance in the workplace. This course identifies the difference between medical and exposure records and the content of these records. Topics in this course include: Types of Records, Handling Records, and Frequently Asked Questions (FAQs). After completing this course, learners will be able to recognize how to properly handle and maintain medical or exposure records.

Format: eLearning - SCORM, eLearning - EduFlex

Languages Available:
- German
- Spanish (Latin America)

Libraries:
- Environmental Health and Safety
- Medical Records

Accident Investigation Overview

#N/A

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline
- Midstream Topics

Active Shooter: Law Enforcement

When an active shooter is in a workplace, people depend on law enforcement to stop the threat. Take this course to learn what to expect from law enforcement officers and what YOU can do to ensure they can do their jobs. This course is ideal for all employees.

Format:

Libraries:
- Not specified
Active Shooter: Prevention and Preparation
By the end of this course, you will be able to recognize the warning signs that someone may be prone to violence and identify what you can do NOW to prepare for an incident involving an active shooter.

Format:
Libraries:
- Not specified

Active Shooter: Run, Hide, Fight
If an active shooter came into YOUR workplace, would you know what to do to survive? Take this course to learn how to make life-or-death decisions about running, hiding or fighting to survive. This course is ideal for all employees.

Format:
Libraries:
- Not specified

Active Shooter: Victims
If there is an active shooter in your workplace, emergency response professionals may not be able to get to victims immediately. In these cases, you may be able to help keep people alive until help arrives. Take this course to learn what YOU can do! This course is ideal for all employees.

Format:
Libraries:
- Not specified

Administrative Roles of the Clinical Research Associate
This course examines the administrative roles and responsibilities of the Clinical Research Associate (CRA) during specific on-site monitor visits conducted at the principal investigator location on behalf of a sponsor. Topics in this course include: Roles and Responsibilities, Monitoring Plan, PSSV and SIV, Source Documents, and Monitoring Functions. After completing this course, learners will be able to identify the general roles and responsibilities of a CRA, with recommended monitoring tasks to be completed at specified time intervals of an ongoing study.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical
- Functional Areas:
  - Clinical: Quality Topics

Administrative Roles of the Clinical Research Coordinator
This course describes the administrative roles and responsibilities of the Clinical Research Coordinator (CRC). The CRC is an individual who coordinates many aspects of a clinical trial at the investigative site. The CRC's tasks are formally delegated to them by the principal investigator (PI) and frequently involve both clinical duties (within their professional scope of practice) and coordination activities. Upon completion of this course, you will be able to identify the CRC role throughout a clinical trial, as well as recognize applicable Good Clinical Practice standards.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical
- Functional Areas:
  - GCP Basics
Aerial Patrol

Aerial Patrol discusses aerial pipeline patrol, reportable conditions, patrol frequency, required documentation, emergency observations, and abnormal operating conditions (AOCs).

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Affirmative Action in the Workplace (For Employers)

Today, federal laws make it illegal to discriminate against a job applicant or an employee because of the person’s race, color, religion, sex, national origin, age, disability, or genetic information. This course addresses the essential features of affirmative action requirements for federal contractors. Topics in this course include discrimination laws, responsibilities of a federal contractor, and the equal opportunity clause. After completing this course, learners will be able to recognize Affirmative Action Plans (AAPs) and their role in aiding compliance with these anti-discrimination laws.

Libraries: Ethics & Corporate Responsibility, HR Compliance & Risk Management
Functional Areas: Corporate Compliance Basics

Age Discrimination

Age discrimination can be particularly challenging when an employer is reducing employee numbers or is managing an aging workforce. This course describes the federal legislation that prohibits age discrimination in the workplace. Topics in this course include: Legislation, Prohibited Practices, Claims, and Helpful Strategies. After completing this course, learners will be able to recognize provisions of the Age Discrimination in Employment Act (ADEA).

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Ethics & Corporate Responsibility, HR Compliance & Risk Management
Functional Areas: Corporate Compliance Basics

Air Permitting Awareness

Air Permitting Awareness is a general overview course that examines the purpose of air permitting, Title V operating permits, stack and fugitive emissions, emissions issues, agency inspections, inspection preparation, and responding to a citation.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics
Air Permitting for Supervisors

Air Permitting for Supervisors is a general overview course that discusses the purpose of air permitting, federal and state operating permits, stack and fugitive emissions, emissions issues, agency inspections, inspection preparation, and responding to Notices of Violation.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Americans with Disabilities Act

The course identifies who is classified as a disabled employee and how these employees are protected under the Americans with Disabilities Act (ADA). This course also discusses the concepts of reasonable accommodation and undue hardship as well as coverage for substance abuse. Topics in this course include: Disability, Legislation, Reasonable Accommodation, and Drugs and Alcohol. After completing this course, learners will be able to recognize who is classified as a disabled employee and how the ADA protects these individuals. Learners will also be able to recognize how to comply with the ADA reasonable accommodation requirement.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:
- HR Compliance

An Introduction to ISO 13485 - The Quality Management System for Medical Devices

The international standard ISO 13485:2016 specifies the requirements for a quality management system that can be used by an organization in one or more stages of the life-cycle. ISO 13485 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations. This course is the first of a two part series. Topics in this course include: ISO 13485:2016, Process Approach, Clauses 4-6, Clauses 7 and 8, and Preparation. This course also addresses specific aspects of ISO 13485 as it relates to the European Union (EU). After completing this course, learners will be able to recognize the requirements of ISO 13485.


Libraries:
- Medical Device GMPs

Functional Areas:
- FDA QSR Basic Concepts
- ISO Standards

Content Bundles:
- Medical Device - GMP

Languages Available:
- French (European) (DEV48)
- German (DEV48)
- Japanese (DEV48)
- Korean (DEV48)
- Chinese (Simplified) (DEV48)
- Spanish (Latin America) (DEV48)

An Introduction to ISO 9001:2015 — The Quality Management System Requirements

This course serves as an introduction to ISO 9001:2015 — the international quality management system requirements standard. This standard specifies requirements to demonstrate an organization’s ability to consistently provide products and services which meet customer satisfaction and applicable statutory and regulatory requirements. However, requirements of this standard are generic and are intended to be applicable to any organization regardless of which products and services are provided. Topics in this course include: Scope, Principles, Certification, Auditing, and Resources. After completing this course, learners will be able to identify the quality management principles of the standard and be able to recognize considerations for selecting a certification body as well as appropriate preparations for certification audits.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Medical Device GMPs

Functional Areas:
- ISO Standards

Languages Available:
- Chinese (Simplified) (DEV60)
- French (European) (DEV60)
- Spanish (Spain) (DEV60)
- German (DEV60)
- Korean (DEV60)
Antitrust Law and Competitor Relationships

Federal antitrust laws are designed to ensure that the basic promise of a free market economy and effective competition is not undermined by unlawful manipulation or collusion between competitors. This course explains how antitrust legislation regulates contact between competitors, and what employers and employees can do to ensure that they are in compliance with US antitrust laws. Topics in this course include: Legislation, Sherman Act, Clayton Act, Federal Trade Commission (FTC), Illegal Agreements, Competitor Interactions, and Helpful Strategies. After completing this course, learners will be able to recognize the antitrust laws that govern competitor interactions as well as their application to everyday business situations.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:

- HR Compliance & Risk Management
- HR Compliance

Appeals and Grievances: Classification of Copayment Issues (Micro)

This course covers real-life scenarios and requires learners to apply knowledge of Part C and Part D appeal and grievance procedures in order to classify copayment issues appropriately. After completing this course, learners will be able to identify the correct classification of copayment issues based on a brief summary of each situation.

Format: eLearning (Editable) - CREATE

Libraries:

- Not specified

Application of GMPs to Analytical Laboratories

Compliance with current Good Manufacturing Practices (cGMP) requirements is essential in order to create products that have quality, purity, proper identity, strength, and are safe. All laboratory analysts must follow cGMPs in order to create effective products and comply with all quality standards. Topics in this course include: Laboratory Documents, Laboratory Practices, Raw Data, Method Validation, Calibration, Training, OOS, and Computer Systems. After completing this course, learners will be able to identify cGMP requirements as they apply to analytical laboratory practices.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs
- GxP Basics

Languages Available:
- French (European)
- German
- Spanish (Spain)

Application of GMPs to Microbiology Laboratories

This course describes the general principles of current Good Manufacturing Practices (cGMPs) and their importance in microbiology laboratories. Topics in this course include: Application, Laboratory Documents, Handling Raw Data, Growth Media, Aseptic Technique, Environmental Monitoring Program, Laboratory Equipment, Training, and OOS Results. After completing this course, learners will be able to identify the importance of handling of raw data and recognize key approaches for ensuring accurate results. This course discusses requirements for both the European Union (EU) and US Food and Drug Administration (FDA).

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical GMPs
- GxP Basics

Languages Available:
- French (European) (PHDV72)
- German (PHDV72)
- Spanish (Spain) (PHDV72)
Approach to Computerized Systems Validation and Compliance

This course describes an approach to the validation and compliance of computerized systems used in the manufacture of pharmaceuticals, biologicals, and medical devices that are required to meet FDA’s regulations. It identifies ways to organize policies and procedures, and plans FDA expects a manufacturing company to establish. This course draws on current industry good practice. Though it also draws on FDA medical device guidance, this course is not intended to describe an approach to developing software that subsequently becomes part of a medical device. This is the second course in a series of four courses. Before taking this course, you should have successfully completed Requirements for Computerized Systems Validation and Compliance.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: 
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas: 
- Computer Systems Validation

Content Bundles: 
- Computer Systems Validation

Languages Available: 
- German
- French (European)
- Chinese (Simplified)
- Japanese
- Korean
- Spanish (Spain)

Asbestos Awareness

Asbestos is known for its hazardous effects on those who work in contaminated areas. This course discusses the components of asbestos along with the safest ways to control and work with asbestos. Topics in this course include: Defining Asbestos, Effects on Health, Limits of Exposure, Controlling Asbestos, Protecting Yourself, and Medical Monitoring. After completing this course, learners will be able to recognize the different types of asbestos, the hazards they pose, how to control asbestos, and how to protect themselves from asbestos exposure.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: 
- Environmental Health and Safety

Functional Areas: 
- EHS Basics

Aspects of Regulatory History

Regulatory standards for conducting clinical trials are in place to protect those conducting and participating in clinical trials. This course describes the regulatory requirements of the US Department of Health and Human Services (HHS), Food and Drug Administration (FDA), and the guidelines of the International Conference on Harmonisation (ICH) necessary to ensure proper and successful clinical trial execution. Topics in this course include: History, Organizations, Regulations, and Guidelines. After completing this course, learners will be able to recognize the impact of ICH guidelines on the industry from a global perspective.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: 
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas: 
- GCP - Clinical Management

Partners: Corexcel

Languages Available: 
- Chinese (Simplified) (GCP22)
- German (GCP22)
- Japanese (GCP22)

Atmospheric Corrosion - Distribution Operations

Atmospheric Corrosion - Distribution Operations examines the requirements for atmospheric corrosion control. This course addresses the corrosion process, surface preparation, attributes of and risk factors for atmospheric corrosion, and protective methods used to control atmospheric corrosion.

Format: 

Libraries: 
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: 
- Midstream Topics
Atmospheric Corrosion - Pipeline Operations

Atmospheric Corrosion - Pipeline Operations explains basic corrosion, atmospheric corrosion, protective measures, corrosion regulations, surface preparation, and coating application. Abnormal operating conditions (AOCs) that may be encountered while inspecting and application of protective coatings to detect and prevent atmospheric corrosion are also included.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Auditing of Computer System Validation to Ensure Data Integrity

FDA inspectors and corporate auditors must be able to recognize the critical aspects of computerized systems and the documentation needed to demonstrate that they are validated. This course provides an approach to inspecting/auditing these systems and covers the detailed review of systems that automate part of the production process or part of a quality system. Topics in this course include: Data Integrity and Governance, Validation and the SDLC, Key Documentation Deliverables, Requirements, Design and Configuration, Implementation and Verification, and Maintenance. After completing this course, learners will be able to recognize validation activities and the maintenance of the validated state as it relates to data integrity. Prerequisites for this course include Introduction to Data Integrity and either the Computerized Systems Inspections in the Medical Device Industry or the QSIT 5 — The Production and Process Controls Subsystem course.

Libraries: Data Integrity
Functional Areas: Quality Assurance
Content Bundles: Data Integrity

Awareness of FDA Inspections for Pharmaceutical Manufacturers

This course covers the basics of FDA inspections of drug manufacturing facilities, including authority, purpose, types, and areas/operations typically inspected. The course also discusses how companies and their personnel should generally handle FDA inspections and interact effectively with Investigators. Topics in this course include: Scope, Inspection Types, Initiation, Handling Inspections, Inspection Coverage, FDA Interaction, and Closeout. After completing this course, learners will be able to identify the basics of FDA inspections of drug manufacturing facilities and how firms should handle FDA inspections and interact effectively with Investigators.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM
Libraries: Pharmaceutical GMPs
Functional Areas: GMP Inspection Readiness, FDA Inspection Readiness
Content Bundles: GMP Inspection Readiness

Backfilling

Backfilling discusses the basic requirements for backfilling pipeline evacuations, including inspection, filling standards, soil conditions, environment considerations, and abnormal operating conditions.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics
Ball Valve Maintenance

Ball Valve Maintenance explains how a ball valve operates, along with many of the different design features and their purpose. It also discusses proper cleaning, lubricating, and maintenance techniques that are unique to ball valve maintenance. Common abnormal operating conditions (AOCs) that may be encountered while inspecting or maintaining valves are identified, including proper reactions.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Basic Corrosion

Basic Corrosion explains basic corrosion, the causes and types of corrosion, bacterial corrosion, and factors such as pH and temperature that affect corrosion rates.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Basic Electronics: PLCs

Basic Electronics: PLCs addresses basic information and hardware components concerning PLCs; principles of PLC operation; applications of PLCs in the natural gas industry; installation, calibration and checkout, documentation, and troubleshooting PLCs; peripheral devices used with PLCs; waveform properties and phase relationships; and ladder logic and other skills associated with programming PLCs.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Basic Electronics: SCADA

Basic Electronics: SCADA addresses SCADA system history, office and field hardware components, communication protocols, installation, calibration, and troubleshooting.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
Basic Radiation Awareness

The general public often thinks radiation exposure only occurs in areas displaying “Caution: Radiation,” or “Danger: Radiation” signs. Actually, in addition to exposure in certain work places, each of us is exposed to natural radiation each day of the year. Topics in this course include: Effects, Limits, Controls, Assessment, and Regulations. After completing this course, learners will be able recognize the types of natural and man-made (ionizing) radiation, where radiation originates, its health effects, principles of protection, and the components of an effective Radiation Protection Program.

| Format: eLearning - SCORM, eLearning - EduFlex |
| Functional Areas: |
| • Environmental Health and Safety |
| • Medical Device - Sales & Marketing |

Basics of Business Finance

The purpose of corporate financial management is to get everyone pulling together to create value. No company can succeed if its people lack skills in managing its money and assets. This course describes the basics of business finance. Topics in this course include: Funding, Balance Sheet, Income and Cash Flow Statements, Ratios, Forecasting, and Common Language. After completing this course, learners will be able to recognize the fundamentals of corporate finance in simple, easy to understand terms. Learners will also be able to recognize how work activities can and do affect the financial health of an organization.

| Format: eLearning - EduFlex, eLearning - SCORM |
| Libraries: |
| • HR Compliance & Risk Management |
| Functional Areas: |
| • Professional Development |

Basics of Cleanroom Operations

Cleanrooms play a major role in preventing product contamination and ensure product sterility and safety. This course describes the general principles and practices relevant to proper cleanroom operations. Topics in this course include: Cleanroom Design, Contamination Control, People and Materials, Validation, and Monitoring. After completing this course, you will be able to recognize how cleanrooms are designed, validated, and operated to ensure product sterility and safety of aseptically produced sterile products.

| Format: eLearning - EduFlex, eLearning - SCORM |
| Libraries: |
| • Not specified |
| Functional Areas: |
| • Aseptic Processing |
| Programs: |
| • Aseptic Processing: Advanced Series |

Basics of Inspections: Beginning an Inspection

This is the first of two courses designed to inform learners of the basic practices during an inspection of a food establishment. This course explores the preparation needed before an inspection and identifies pre-inspection issues. Topics in this course include: Preparation, Pre-inspection Issues, HACCP, Product Protection, Hazards, and Corrective Actions. After completing this course, learners will be able to identify the purpose of a Hazard Analysis Critical Control Point (HACCP) plan and recognize the purpose of corrective actions.

| Format: eLearning (Editable) - CREATE, eLearning - EduFlex, eLearning - SCORM |
| Libraries: |
| • FDA Inspections and Enforcement |
| Functional Areas: |
| • FDA Inspection Readiness |
| Partners: FDA |
Basics of Inspections: Issues and Observations
FDA39

This is the second of two courses designed to inform the learner of the basic practices during an inspection of a food establishment. This course explores the issues and observations that must be examined during an inspection, including: processing equipment, employee practices, food storage/display, water supply and plumbing, and pest control. Topics in this course include: Employee Practices, Processing Equipment, Food Storage and Display, Cross-contamination, Water Supply, Food Sampling, Inspection Report, and Closing Conference.

After completing this course, learners will be able to identify the unsatisfactory practices that lead to contaminated food. Learners will also be able to recognize proper sampling procedures. Lastly, learners will be able to identify what to include in an inspection report and how to conduct a closing conference at the conclusion of an inspection.


Libraries:  
- FDA Inspections and Enforcement

Functional Areas:  
- FDA Inspection Readiness

Partners: FDA

Basics of PhRMA Code
PHSM01

For members of PhRMA to reaffirm their commitment to following the highest ethical standards as well as all legal requirements while promoting products to the medical community.


Libraries:  
- Pharmaceutical - Sales & Marketing

Functional Areas:  
- Corporate Ethics
- Sales Compliance

Content Bundles:  
- Corporate Compliance - Pharmaceutical

Basics of the AdvaMed Code
MDSM01

It is crucial for all Medical Technology companies to understand the guidelines of the Advanced Medical Technology Association (AdvaMed) Code and how they impact interactions with Health Care Professionals (HCPs). This course discusses the Basics of the AdvaMed Code. Topics in this course include: Code, Education and Business Meetings, Consulting, Evaluation and Demonstration Products, and Gifts and Meals. After completing this course, learners will be able to recognize how the AdvaMed Code guides interactions with HCPs.


Libraries:  
- Medical Device - Sales & Marketing

Functional Areas:  
- Vendor Credentialing

Content Bundles:  
- Corporate Compliance - Medical Device

Languages Available:
- Spanish (Latin America) (MDSM01)
- German (MDSM01)
- French (European) (MDSM01)
- Chinese (Simplified) (MDSM01)
- Japanese (MDSM01)

Batch Record Reviews
PHA53

Pharmaceutical batch records are essential to ensure that regulatory and product quality attributes are achieved. This course describes how to properly perform a batch record review. Topics in this course include: Regulations, Manufacturing Records, Packaging Records, Laboratory Records, and Issues and Deviations. After completing this course, learners will be able to identify the GMP and cGMP requirements for batch records and recognize how to maintain GMP and cGMP compliance throughout the review process. The regulatory requirements of FDA are addressed with reference also made to the requirements of the EU.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:  
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:  
- Batch Records

Partners: FDA

Languages Available:
- French (European) (PHA53)
- German (PHA53)
- Spanish (Spain) (PHA53)
Benzene

One of the most beneficial and most dangerous compounds in manufacturing today is benzene. This course outlines the hazards of benzene and ways to minimize those hazards to the workforce. Topics in this course include: Benzene and Its Risks, Hazards of Benzene, Monitoring Exposure, Controls, and Fire and Spill Hazards. After completing this course, learners will be able to recognize practices to prevent and handle benzene fires and spills in the workplace.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:  
- Environmental Health and Safety
- EHS - Chemicals

Best Practices: Modest Meals

This course describes the best practices and requirements under the AdvaMed Code for providing modest meals to healthcare professionals as a part of medical device sales presentations.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:  
- Medical Device - Sales & Marketing
- Corporate Ethics

BIMO: Clinical Investigator

This course focuses on the responsibilities of a Clinical Investigator (CI) who participates in clinical research involving unapproved test articles that are under FDA's jurisdiction. Topics in this course include: Purpose, Regulations, Managing Inspections, Develop a Strategy, Critical Elements, and FDA Options. After completing this course, learners will be able to recognize FDA's role in CI compliance and regulatory oversight. Learners will also be able to identify the responsibilities of CIs and recognize the regulations that apply to CIs.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:  
- FDA BIMO Course Series
- Clinical: Quality Topics

BIMO: General Inspection Assignment Process

This is the second in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo Bioequivalence inspections. This course provides an overview of the general inspection assignment process, site selection, background materials used in a BIMO inspection, and regulatory consequences of the BIMO program.

Format: eLearning - HIP2
Libraries:  
- FDA BIMO Course Series
- Clinical: Quality Topics
BIMO: In Vitro Bioequivalence Program Part I

FDA inspects the facilities of the sponsors or their contractors who conduct bioequivalence studies, under the In Vivo Bioequivalence Compliance Program. It is one of the seven compliance programs of the Bioresearch Monitoring (BIMO) Program. Included in the FDA inspections are the clinical facilities where bioequivalence studies are conducted (i.e., subjects are enrolled, dosed, and biological samples are collected) and analytical facilities where biological samples are analyzed to determine the concentrations of the drug. This course will introduce you to some brand name and generic drugs, explain the importance of bioavailability, and describe the underlying concept of bioequivalence for comparison of drug performance. This course will also discuss the implementation of the in vivo bioequivalence compliance program.

Format: eLearning - HIP2

Libraries: FDA BIMO Course Series

Functional Areas: Clinical: Quality Topics

Partners: FDA

BIMO: In Vivo Bioequivalence Program Part II

FDA inspects the facilities of the sponsors or their contractors who conduct bioequivalence studies, under the In Vivo Bioequivalence Compliance Program. It is one of the seven compliance programs of the Bioresearch Monitoring (BIMO) Program. Included in the FDA inspections are the clinical facilities where bioequivalence studies are conducted (i.e., subjects are enrolled, dosed, and biological samples are collected) and analytical facilities where biological samples are analyzed to determine the concentrations of the drug. This course will introduce you to the challenges of inspecting clinical and analytical facilities and the various technical terms commonly used in bioavailability and bioequivalence studies.

Format: eLearning - HIP2

Libraries: FDA BIMO Course Series

Functional Areas: Clinical: Quality Topics

Partners: FDA

BIMO: Part 50 & 56 -- Institutional Review Boards (IRBs)

This is the third in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo Bioequivalence inspections. This course provides an overview of the regulations applicable to the protection of human subjects who participate in clinical research typically involving test articles which are unapproved for marketing, but approved for research by FDA.

Format: eLearning - HIP2

Libraries: FDA BIMO Course Series

Functional Areas: Clinical: Quality Topics

Partners: FDA

BIMO: Sponsor/Monitor Responsibilities

This course focuses on the responsibilities of sponsors and monitors of clinical research involving unapproved test articles that are under the jurisdiction of the FDA.

Format: eLearning - HIP2

Libraries: FDA BIMO Course Series

Functional Areas: Clinical: Quality Topics

Partners: FDA
Biotechnology: An Overview of Compliance Considerations

This course provides an overview of the fundamental compliance issues impacting the biotechnology industry. Topics in this course include: Biotechnology-Derived Products (BDPs), Cell Culture, Antibody Production, Manufacturing Controls, Processing and Filling, BDP Controls, and Testing. After completing this course, learners should recognize what a biotechnology-derived product is, identify how FDA regulates them, and identify various controls for biotechnology-derived products.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Pharmaceutical GMPs

Functional Areas:

• Biotechnology

Partners: FDA

Bloodborne Pathogens -- General Industry

Employees who are regularly exposed to bloodborne pathogens run the risk of contracting serious diseases due to that exposure. This course addresses those potential risks and the ways employees can protect themselves from those risks. Topics in this course include: Exposure Control Plan, Controls, PPE, and Exposure Response. After completing this course, learners will be able to identify the risks of working around bloodborne pathogens, the controls in place to eliminate or reduce those risks, and the equipment that can help keep employees safe.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:

• Environmental Health and Safety

Functional Areas:

• EHS Basics

Bloodborne Pathogens -- Healthcare Workers

This course provides an overview of bloodborne pathogens in the healthcare setting. After completing this course, participants will be able to identify bloodborne pathogens in the workplace, and recognize the different ways a person can be exposed to such substances. Participants will also recognize best practices in the management of these substances and effective ways to minimize the risks of exposure.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

• Environmental Health and Safety
• Healthcare: General
• Medical Device - Sales & Marketing
• Pharmaceutical - Sales & Marketing

Functional Areas:

• Vendor Credentialing
• Medical Device EHS Basics

Content Bundles:

• Vendor Credentialing
• EHS for Life Science Companies - Basics

Languages Available:

Spanish (Latin America)
German
French (European)
Chinese (Simplified)
Japanese

Brazil’s Technical Regulations for Medical Devices: RDC 16/2013, 67/2009, and 23/2012

This course discusses Brazil's technical regulations for medical devices, including RDC 16/2013 for Good Manufacturing Practices (GMPs) of Medical Devices and In Vitro Diagnostic Devices (IVDs), RDC 67/2009 for Technovigilance Requirements for Registration Holders, and RDC 23/2012 for Field Action Requirements. Topics in this course include: Background, Elements, and Applications. After completing this course, learners will be able to identify each of these regulations and recognize the practical actions to use in the normal course of business to ensure that the regulations are adhered to.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

• Global Regulatory
• Medical Device GMPs

Functional Areas:

• Medical Device

Languages Available:

Portuguese (Brazil)
### Broker and Agent Training Exam

This is the Broker and Agent Training Exam.

**Format:** eLearning - Exam

**Libraries:**
- Medicare Broker/Agent Training
- Medicare Plan Broker Training

### Building Customer Loyalty

This course teaches the skills needed by employees at all levels of a company to create loyalty, and to impact the company's profitability in a positive way. Topics in this course include: Creating Loyalty, Words, Actions, Leadership, Turnoffs, and Rebuilding. After completing this course, learners will be able to recognize the skills needed to build customer loyalty. Learners will also be able to recognize the importance of customer loyalty to them personally as well as to the company.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- HR Compliance & Risk Management
- Professional Development

### Business Practices to Protect Personal Health Information

This course provides all employees and associates with knowledge of the privacy and security practices for health plans, as required by the Health Insurance Portability and Accountability Act (HIPAA). This course includes updated requirements that were included in the Health Information Technology for Economic and Clinical Health Act (HITECH). Employees will learn the basic principles of health information privacy and security, how they impact the organization, and how they apply to everyday work situations. The course also covers patients' rights under HIPAA, and the consequences for violating privacy and security practices.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Libraries:**
- HIPAA
- Healthcare: HIPAA

### Canadian Medical Device Regulations

This course introduces the Canadian medical device regulations. This course identifies the scope and applicability of the Canadian Medical Devices Regulation (CMDR) that was last amended on February 13, 2017. Topics in this course include: Regulatory Agencies, Definition, Medical Device Licensing, Post Approval, and CMDR vs ISO 13485. After completing this course, learners will be able to identify the requirements to market devices in Canada.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Global Regulatory
- Medical Device GMPs
Care and Handling of Drug Product Components, Labeling, Containers, and Closures

It is crucial to understand and follow cGMP regulations related to components, labeling, containers, and closures of drug products. This course describes how to implement control handling and testing of drug products while meeting cGMP regulations. Topics in this course include: Receipt and Holding, Sampling, Vendor Certification, and Documentation. After completing this course, learners will be able to identify the proper procedures for the receipt, sampling, storage, testing, and record keeping of drug product components and containers and closures.

Languages Available:
- Chinese (Simplified) (PHA41)
- Japanese (PHA41)
- German (PHA41)
- French (European) (PHA41)
- Spanish (Spain) (PHA41)

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Partners: FDA

Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- Packaging,
- Warehousing and Distribution

Cast Iron Joints

Cast Iron Joints discusses the common problems associated with cast iron pipe, such as graphitization, and explains the methods for cast iron pipe joint repair, including joint clamps and encapsulation. Abnormal operating conditions (AOCs) are also discussed.

Languages Available:
- Chinese (Simplified) (EGY-410CAST)
- Japanese (EGY-410CAST)
- German (EGY-410CAST)
- French (European) (EGY-410CAST)
- Spanish (Spain) (EGY-410CAST)

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Partners: FDA

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Cathodic Protection - Rectifier Inspections

Cathodic Protection - Rectifier Inspections explains cathodic protection systems, rectifier types, rectifier inspections, and calculating rectifier efficiency. Abnormal operating conditions (AOCs) that may be encountered while inspecting and testing rectifiers are included.

Languages Available:
- Chinese (Simplified) (EGY-502RECT)
- Japanese (EGY-502RECT)
- German (EGY-502RECT)
- French (European) (EGY-502RECT)
- Spanish (Spain) (EGY-502RECT)

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Partners: FDA

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Cathodic Protection Criteria

Cathodic Protection Criteria explains the criteria for cathodic protection systems, methods of collecting specific data, annual surveys, and data evaluation and reporting. Abnormal operating conditions (AOCs) that may be encountered while installing test stations are included.

Languages Available:
- Chinese (Simplified) (EGY-505CRIT)
- Japanese (EGY-505CRIT)
- German (EGY-505CRIT)
- French (European) (EGY-505CRIT)
- Spanish (Spain) (EGY-505CRIT)

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Partners: FDA

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
Cathodic Protection Troubleshooting

Cathodic Protection Troubleshooting explains cathodic protection systems; equipment needed for troubleshooting; safety precautions; and troubleshooting procedures for locating rectifier faults, cable breaks, insulators, and contacts. Abnormal operating conditions (AOCs) that may be encountered while troubleshooting cathodic protection systems are included.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

CE Certification for Medical Devices

This course describes information about compliance of medical devices in accordance with the European Medical Device Regulations (MDR). Topics in this course include: Classification and Conformity Routes, General Requirements, Design and Construction, Technical File and Design Dossier, Quality Management System (QMS), Documentation, and Vigilance. After completing this course, learners will be able to recognize essential requirements and harmonized standards for medical devices.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Medical Device GMPs
- Global Regulatory

Functional Areas:
- EU Market Access
- EU MDD
- EU Regulations

CFDA Order No. 25 -- Good Clinical Practices for Medical Devices

China Food and Drug Administration (CFDA) Order No. 25 — Good Clinical Practice for Medical Devices was enacted to strengthen the administration, supervision, and management of clinical trials medical devices. Topics in this course include: General Provisions, Preparation Before Clinical Trials, Guarantee of Rights and Interests of Subjects, Clinical Trial Protocol, Responsibilities of Ethics Committee, Responsibilities of Sponsors, Responsibilities of Clinical Trial Institutions and Investigators, Recording and Reporting, and Management of Investigational Medical Devices.

After completing this course, learners will be able to identify participating regulatory agencies. Learners will also be able to identify the rights of clinical trial subjects and the responsibilities of investigators, sponsors, the administrative department, and the ethics committee. Lastly, learners will be able to recognize the documentation and reporting requirements for clinical trials.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Global Regulatory
- Medical Device GMPs

Functional Areas:
- Medical Device
- Global Market Access - Medical Device

CGIs and Flame Ionization Units

CGIs and Flame Ionization Units examines categories of combustible gas instruments; characteristics and properties of natural gas; the fire triangle; LELs; UELs; OSHA safe working levels; carbon monoxide hazards and detection; and the use, operation, and inspection of combustible gas indicators and flame ionization units.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
Change Control

The control of change is very important in the regulated industries of drug products, biologics, and medical devices. Changes to processes, material, equipment, and people can have a direct impact on the quality, effectiveness, and safety of the product. This course presents the concept of change control by placing the learner in the role of a change control manager. Topics include key steps, change indicators, and notification of governing bodies. After completing this course, you will be able to identify what a change control consists of and recognize the basics of the change control model. You will also be able to recognize the importance of a change control. Lastly, you will be able to recognize the key elements of an effective change control system.


Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs
- Global Regulatory

Functional Areas:
- Pharmaceutical GMP Basics

Partners: FDA

Languages Available:
- Chinese (Simplified) (PHA35)
- Japanese (PHA35)
- German (PHA35)
- French (European) (PHA35)
- Spanish (Spain) (PHA35)

Characteristics and Properties of Natural Gas

Characteristics and Properties of Natural Gas explores the composition, properties, and flammable characteristics of natural gas; the history of natural gas use; gas leak and carbon monoxide monitoring; and natural gas safety.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Languages Available:
- Chinese (Simplified) (EGY-103GAS)
- Japanese (EGY-103GAS)
- French (European) (EGY-103GAS)
- German (EGY-103GAS)
- Spanish (Spain) (EGY-103GAS)

Cleanroom Cleaning, Sanitization, and Disinfection

In order to achieve safe and effective products, manufacturers of sterile product must employ various contamination control methods, such as cleaning, sanitization, and disinfection in the cleanroom. Topics in this course include: Contamination, Cleaning, Sanitization and Disinfection, and Additional Considerations. After completing this course, learners will be able to recognize why cleaning and sanitization are critical to contamination control in the cleanroom. Learners will also be able to identify the differences between cleaning, sanitizing, and disinfecting. Lastly, learners will be able to recognize proper basic cleaning procedures as well as critical parameters for effective sanitization.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Not specified

Functional Areas:
- Aseptic Processing

Programming:
- Aseptic Processing: Advanced Series

Languages Available:
- Chinese (Simplified) (Aseptic08)
- French (European) (Aseptic08)
- German (Aseptic08)
- Japanese (Aseptic08)
- Spanish (Spain) (Aseptic08)

Clinical Trial Audits and Consequences of Non-Compliance

Sponsors can put measures in place in an attempt to dissuade researchers from being noncompliant, but those measures are only as effective as the personnel applying them. This course will provide a description of the clinical trial audit process and how audits help to ensure trials are conducted in accordance with regulatory requirements. Topics in this course include: Clinical Trial Audit, FDA Inspection, and Noncompliance. After completing this course, learners will be able to identify FDA standards for conducting and reporting clinical site inspections, as well as recognize FDA's system for classifying inspections and taking corrective action.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- GCP - Clinical Management

Content Bundles:
- Global Clinical Operations

Languages Available:
- Chinese (Simplified) (GCP21)
- German (GCP21)
- Japanese (GCP21)
Close Interval Surveys

Close Interval Surveys discusses the purpose and requirements of a close interval survey, required equipment, steps of a survey, survey impediments and solutions, data loggers, and documentation. Abnormal operating conditions (AOCs) that may occur during a close interval survey are included.

Format:
Libraries:
• DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
• Midstream Topics

Code of Business Conduct

All employees need to be aware of their company's Code of Business Conduct. This course describes the Code of Business Conduct and basic ethical principles and guidelines for conducting business with our partners, clients, and competitors. Topics in this course include: Obeying the Law, Conflicts of Interest, Gift Policies, Protected Information, and Ethical Conduct. After completing this course, learners will be able to identify the basic principles that make up the Code of Business Conduct.

Libraries:
• Ethics & Corporate Responsibility

Functional Areas:
• HR Compliance

Code of Conduct

Trust is the cornerstone of any long-term business relationship. Our responsibility is to earn that trust every day by acting in an ethically and legally responsible manner that is beyond reproach. This course addresses the standards of conduct outlined in our Company's Code of Conduct. Topics in this course include: Compliance with the Code, Protecting Information, Conflicts of Interest, Government Contracts, and Reporting Violations. After completing this course, learners will be able to identify our Company's standards which must be applied to activities they perform on a daily basis and help build the crucial foundation of trust that our customers and members rely on every day.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM
Libraries:
• Healthcare: General

Functional Areas:
• Healthcare: Compliance Topics

Collecting Samples and Establishing Limits for Cleaning Validation

GMP regulations require that equipment used in the manufacturing of a drug, medical device, or biologic product be cleaned in such a way as to ensure that the quality, purity, and safety of a product will not be adversely affected. This course explains methods in which to collect samples and the need for establishing limits of cleanliness in cleaning validation. Topics in this course include: Locations, Methods, Pros and Cons, Approaches, Influencing Factors, and Documentation. After completing this course, you will be able to identify the advantages and disadvantages of common sampling methods. You will also be able to recognize the need for established limits of cleanliness in cleaning validation, as well as be able to utilize formulas to derive safe, practical cleaning limits.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
• Pharmaceutical GMPs

Functional Areas:
• Pharmaceutical GMPs
• GMPs - Process Validation

Languages Available:
French (European)
German
Spanish (Spain)

Partners: FDA
Combination Products – cGMP Requirements

FDA has issued a regulation on the current good manufacturing practice (cGMP) requirements applicable to combination products in an effort to improve the consistency of the regulatory requirements and implementation. This course discusses cGMP requirements and FDA rules that relate to combination products. Topics in this course include: Background, Final Rule, Compliance, The Office of Combination Products, and Post-Approval Modifications. After completing this course, learners will be able to recognize the four different types of combination products and the scope of the regulation in 21 CFR Part 4. They will also be able to identify how to comply with each of the drug, device, and biological product provisions and handle post-marketing events.


Languages Available: Chinese (Simplified) (PHDV93) Japanese (PHDV93)

Combustible and Flammable Liquids

Combustible and flammable liquids are often the root cause of many fires and explosions in the workplace. This course describes safety precautions for controlling, transferring, and storing combustible and flammable liquids. Topics in this course include: Hazards, Controls, and Transfer and Storage. After completing this course, learners will be able to recognize how to safely transport and store flammable and combustible liquids.

Format: eLearning - EduFlex, eLearning - SCORM

Languages Available: Spanish (Latin America)

Complaint Management for Medical Device Manufacturers

It is very important for manufacturers to properly respond to reports of alleged medical device problems. This course covers the FDA regulations for reporting these problems. Topics include: Definition, System Elements, Complaint File, Investigation, MDR, and Complaint Analysis. After completing this course, you will be able to identify the primary elements in an effective complaint handling system; recognize how to document, evaluate, and investigate complaints; recognize complaints that must be reported under FDA regulations; and identify the importance of statistical techniques in analyzing complaint trends.


Complaint Management for Pharmaceutical Manufacturers

There are specific requirements regarding how companies must receive, investigate, document, file, and report customer complaints. This course identifies the primary elements in an effective pharmaceutical complaint handling system. Topics in this course include: System Elements, Complaint File, Investigation, Adverse Drug Experiences, and Complaint Analysis. After completing this course, learners will be able to identify the key elements in building an effective pharmaceutical complaint handling system.

Format: eLearning - EduFlex, eLearning - SCORM

Languages Available: German (PHA71) French (European) (PHA71) Chinese (Simplified) (PHA71) Japanese (PHA71) Korean (PHA71)
ComplianceWire Administrator Certification Exam – Advanced

No description specified

Format: eLearning - Exam

Libraries:

- Not specified

ComplianceWire Administrator Certification Exam -- Basic

No description specified

Format: eLearning - Exam

Libraries:

- Not specified

ComplianceWire Advanced Administrator Certification

This is the exam for ComplianceWire Advanced Administrator Certification.

Format: eLearning - Exam

Libraries:

- Not specified

ComplianceWire Basic Administrator Certification

This is the exam for ComplianceWire Basic Administrator Certification.

Format: eLearning - Exam

Libraries:

- Not specified

Compressed Gas

Handling compressed gases exposes employees to many potential hazards. It is important to understand the proper ways to work with compressed gases to avoid these hazards. This course discusses the common hazards of compressed gases and the methods to safely store and control them. Topics in this course include: Defining Compressed Gasses, Engineering Controls, Work Practice Controls, PPE, Storage, Pressure, Acetylene, and Responding. After completing this course, learners will be able to recognize the hazards associated with compressed gases, the proper safety methods for handling and storing compressed gas cylinders, and the steps of authorized employees to handle leaks.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:

- Environmental Health and Safety
- Gas Safety

Compressor Operation: Compressor Cylinders

Compressor Operation: Compressor Cylinders examines the major components of a compressor cylinder, compressor valve operation and classification of cylinders, troubleshooting and safely changing compressor cylinders, maximizing available horsepower for compressor efficiency, and piston rings and packing materials.

Format:

Libraries:

- DOT Operator Qualification - Oil And Gas Pipeline
- Midstream Topics
Compressor Operation: Gas Path Integrity

Compressor Operation: Gas Path Integrity addresses gas path integrity and maintenance to minimize compromises; horizontal and vertical rod runout; critical compressor clearances involved in gas path integrity, including measurement, records, acceptable limits, and adjustment; leak testing methods and repair; run-time verification tests; and proper torquing of threaded fasteners.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Compressor Operation: Power Cylinder Balancing

Compressor Operation: Power Cylinder Balancing addresses the importance of balanced engine power cylinders, correct procedures and methods for balancing power cylinders, and how engine performance-monitoring tools are used to balance power cylinders.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Compressor Operation: Turbine Units

Compressor Operation: Turbine Units examines the operational process of a turbine compressor unit. This course addresses theory of operation for turbine and centrifugal compressor units; major components of the turbine unit; purposes of fuel gas, lubrication, and air systems; key components of wet and dry seal systems; startup, loading, unloading, and shutdown procedures for turbine compressor units; and maintenance disadvantages.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Compressor Station Operations and Safety

Compressor Station Operations and Safety introduces compressor station operations, prime movers, compressors, fuel meter and auxiliary buildings, as well as the hazards and precautions of compressor stations. Common abnormal operating conditions (AOCs) that may be encountered while performing work at a compressor station are identified, including possible responses.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
Compressor Stations: Design and Emergency Planning

Compressor Stations: Design and Emergency Planning discusses the design and safety features that are required in a compressor station. The safety factors include boundaries, building design, ventilation, flammable materials storage, pressure limiting devices, gas detectors, fire sensors, emergency shutdown systems, and emergency planning. Abnormal operating conditions (AOCs) that may be encountered while performing work at a compressor station are identified, including possible responses.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline
- Midstream Topics

Functional Areas:
- EHS - Ergonomics

Computer Workstation Safety

Computer workstations can be a source of nagging and debilitating Repetitive Stress Injuries (RSIs). This course addresses causes and symptoms of RSIs at computer workstations and ways to prevent those injuries. Topics in this course include: RSIs, Symptoms, Prevention, Exercises, and Laptop Safety. After completing this course, learners will be able to identify the symptoms of RSIs and find ways to stay healthy and prevent these injuries while working at a computer workstation.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Environmental Health and Safety
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:
- EHS - Ergonomics

Computerized Systems Inspections in the Medical Device Industry

This course has been designed to assist FDA inspectors in recognizing the critical aspects of computerized systems in the medical device industry. This course explains how computerized systems are used in the medical device manufacturing process and provides an approach to inspecting these systems. This course does not cover the detailed review of software that forms part of a medical device; it covers only inspection of systems that automate part of the device production process or part of the quality system. Before taking this course, users should complete Requirements for Computerized Systems Validation and Compliance and Approach to Computerized Systems Validation and Compliance.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:
- Computer Systems Validation

Content Bundles:
- Computer Systems Validation

Languages Available:
- German (DEV59)
- French (European) (DEV59)
- Chinese (Simplified) (DEV59)
- Japanese (DEV59)
- Korean (DEV59)
- Spanish (Spain) (DEV59)
# Computerized Systems Inspections in the Pharmaceutical Industry

This course explores how FDA personnel recognize the critical aspects of computerized systems in the pharmaceutical industry during Pre-Approval and routine current Good Manufacturing Practices (cGMP) inspections. The course explains how computerized systems are used in the pharmaceutical manufacturing process and provides an approach to inspecting these systems. Topics in this course include: Use, Inspectional Approach, Focus, and Regulations and Guidelines. After completing this course, learners will be able to recognize where computerized systems are used in the pharmaceutical manufacturing process. Learners will also be able to recognize FDA's approach to inspecting computerized systems. Learners will also be able to identify the levels of review that may be used and what comprises each level.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- FDA Inspections and Enforcement

**Functional Areas:**
- Computer Systems Validation

**Content Bundles:**
- Computer Systems Validation

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# Conducting Annual Product Reviews

This course identifies regulations for manufacturers conducting annual reviews of pharmaceutical products. Topics in this course include: APR Requirements, Benefits of APRs, APR Organization and Content, and Quality Metrics. After completing this course, learners will be able to recognize the benefits of conducting an Annual Product Report (APR), and how to organize an APR.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Medical Device GMPs
- Pharmaceutical GMPs

**Functional Areas:**
- Pharmaceutical GMP Basics

**Partners:** FDA

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# Confidentiality, Intellectual Property Protection, and Information Security

Every day, employees may come into contact with information that must be protected. In order to preserve the confidentiality, integrity, and availability of this information, each employee must recognize information that is considered sensitive and be able to protect it. This course defines sensitive information, including intellectual property and trade secrets, and teaches employees how to protect it. Topics in this course include: Legal Protection, Company Protection, and Responses. After completing this course, learners will be able to identify what information is considered sensitive and how they can protect sensitive information and intellectual property, including how to respond to a request by a third party for this information.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Libraries:**
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

**Functional Areas:**
- Corporate Compliance Basics

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# Confined Space Entry

Many work sites contain spaces that are considered “confined spaces.” Employees who work in confined spaces face an increased risk of injury or death due to oxygen deficiency or toxic atmospheres and other increased physical hazards such as engulfment or fire. Topics in this course include: Hazards and Detection, Control, and Personnel Responsibilities. After completing this course, learners will be able to recognize a confined space, the potential hazards of a confined space, and the proper procedures for working in one.

**Format:** eLearning - SCORM, eLearning - EduFlex

**Libraries:**
- Environmental Health and Safety

**Functional Areas:**
- EHS Basics

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Languages Available:
- German
- French (European)
- Chinese (Simplified)
- Japanese
- Korean
- Spanish (Spain)
Contractor Safety

Contractor Safety examines basic safety principles for natural gas and hazardous liquids pipeline workers. Course topics include guidelines, emergency procedures, communication, recordkeeping, and equipment and operations.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Copayment Issue Classification Quiz 1 (Booster #1)

This quiz serves as a booster to the Classification of Copayment Issues micro course that covered the classification of copayment issues. Topics in this course include: Overview and Challenge. After completing this course, learners will be able to identify the correct classification of copayment issues.

Format: eLearning (Editable) - CREATE

Libraries: Not specified

Copayment Issue Classification Quiz 2 (Booster #2)

This quiz serves as a second booster to the Classification of Copayment Issues micro course that covered the classification of copayment issues. Topics in this course include: Overview and Challenge. After completing this course, learners will be able to identify the correct classification of copayment issues.

Format: eLearning (Editable) - CREATE

Libraries: Not specified

Copayment Issue Classifying Examples (Booster #3)

This course serves as a third booster to the Classification of Copayment Issues micro course. This course describes case studies detailing calls between customer service representatives and health plan members. Each case study examines the calls, pauses to ask learners what the member issues are and how they are categorized, and continues with the conclusion of the calls. Topics in this course include: Overview, Case Study 1, and Case Study 2. After completing this course, learners will be able to identify the correct classification of copayment issues based on the case studies that are presented.

Format: eLearning (Editable) - CREATE

Libraries: Not specified

Corporate Emergency Management Plan

Corporate Emergency Management Plan explains how planning will help management provide key corporate resources to assist operational assets responding to an emergency.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics
Corrective and Preventive Actions

Corrective and preventive actions (CAPA) can prevent continuing production problems, high scrap rates, product failures, customer dissatisfaction, and harm to a user or patient. This course describes the regulatory requirements for the corrective and preventive actions procedures. Topics in this course include: Quality System, CAPA Program, Nonconformities, Root Cause Analysis, and Change Control. After completing this course, learners will be able to recognize the applicable regulatory requirements of implementing an effective CAPA procedure.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Languages Available:
- German (PHA70)
- Japanese (PHA70)
- Chinese (Simplified) (PHA70)

Courtroom Testimony

This course will introduce you to your role if you are called as an FDA witness, including grand jury, deposition, declaration, and courtroom testimony. Topics in this course include: Types of Testimony, Preparation, Conduct, On the Stand, and After Testimony. After completing this course, learners will be able to recognize the types of testimony, ways to prepare for testimony, the fundamental characteristics of appropriate courtroom conduct, and the components of effective testimony.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Current Interrupters

Current Interrupters defines current interrupters and their basic uses, configurations, features, and installation instructions for close interval surveys. Abnormal operating conditions (AOCs) associated with current interrupters are included.

Format:

Languages Available:
- English (EGY-244CI)

Damage Prevention

Damage Prevention explains the requirements for locating and marking underground facilities before excavation work may take place. Some of the main topics include the one-call system, locating underground facilities, marking methods, along with public and contractor education. DOT standards and B31Q Tasks that are relevant to damage prevention are listed. Common abnormal operating conditions (AOCs) are included.

Format:
Data Integrity for Clinical Research Staff

Clinical research staff must be aware of the potential and inherent risks to data integrity. Topics in this course include: FDA Directions, Roles, and Errors. After completing this course, learners will be able to identify the role of clinical staff in maintaining data integrity, and identify various challenges to data integrity.

**Languages Available:**
- Chinese (Simplified) (DATA05)
- German (DATA05)
- French (European) (DATA05)
- Spanish (Spain) (DATA05)

**Format:**
eLearning - SCORM, eLearning - EduFlex, eLearning (Editable) - CREATE

**Libraries:**
- Data Integrity

Data Integrity for Quality Control Laboratories

To ensure the quality of raw materials, in-process materials, and finished goods, laboratory data integrity is of great importance in current Good Manufacturing Practices (cGMP) for the US Food and Drug Administration (FDA)-regulated industry. This course focuses on data integrity in the Quality Control (QC) laboratory. Topics in this course include: History, Strategies for Control, and Ethics. After completing this course, learners will be able to recognize potential strategies for maintaining data integrity and the consequences of noncompliance, and identify the types of data integrity issues found by FDA.

**Languages Available:**
- Chinese (Simplified) (DATA04)
- German (DATA04)
- French (European) (DATA04)
- Spanish (Spain) (DATA04)

**Format:**
eLearning - SCORM, eLearning - EduFlex, eLearning (Editable) - CREATE

**Libraries:**
- Data Integrity

Data Integrity: The Role of Quality Assurance for Data Integrity

Clinical trial data integrity has traditionally been an integral part of quality assurance. This course describes quality assurance in the light of new data collection methods and procedures. Topics in this course include: Overall Approach to Quality, Quality Activities, and Documentation. After completing this course, learners will be able to identify the role of Quality Assurance in data integrity, and recognize regulatory compliance auditing and QMS auditing.

**Languages Available:**
- French (European) (DATA03)
- German (DATA03)
- Spanish (Spain) (DATA03)
- Chinese (Simplified) (DATA03)

**Format:**
eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**
- Data Integrity

Data Privacy Breach Simulation

This is a mock privacy breach simulation to assess learners' knowledge of the process and procedures necessary in the event of an actual breach. Dealing with potential breaches is a stressful and time sensitive time. This data privacy simulation is geared to assist you in a proactive manner to address these situations and to be prepared. Topics in this simulation include a simulation of a data breach. After completing this simulation, learners will be able to recognize their own levels of knowledge about privacy breach processes and procedures. Learners will also be able to recognize their ability to handle privacy breaches. Not just security breaches but privacy by design will need to be considered.

**Format:**
eLearning (Editable) - CREATE

**Libraries:**
- Not specified
DEA Compliance

Today, many organizations use regulations for controlled substances to keep their facilities, production processes, and employees safe. This course explains the regulations found in 21 CFR Chapter 2 governing the manufacture and distribution of drugs classified as controlled substances by the Controlled Substances Act (CSA), and as enforced by the Drug Enforcement Agency (DEA). Topics in this course include: DEA’s Role, Classifications, Registration, Facility Controls, Production Controls, Employee Controls, and Recordkeeping. After completing this course, learners will be able to identify how the DEA enforces the laws and associated regulations under the CSA.


Libraries: Pharmaceutical GMPs

Functional Areas: Pharmaceutical GMP Basics

Deficit Reduction Act: False Claims and Employee Protections Training

This course covers the Deficit Reduction Act of 2005 (DRA) and provides awareness of the mandates and provisions that must be provided to employees of a healthcare entity. The course also includes information on the Fraud Enforcement and Recovery Act (FERA) that was signed into law by the President on May 20, 2009 and the Affordable Care Act (ACA) signed into law on March 23, 2010. Topics in this course include: Definitions, State Acts, Whistleblowers, and Compliance. After completing this course, learners will be able to recognize both federal and state laws enacted to reduce the amount of fraud and abuse within the Medicare reimbursement system.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Healthcare: General

Functional Areas: Healthcare: Compliance Topics

Dehydration of Natural Gas

Dehydration of Natural Gas addresses why water is controlled or removed from natural gas and gives an overview of the three main processes: hydrate inhibition, glycol dehydration, and solid desiccants. It describes where each of these processes is likely to be used and the factors that can influence their performance.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Dehydration With Triethylene Glycol

#N/A

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics
Design Control Regulations for Medical Device Manufacturers

Manufacturers of medical devices are responsible for ensuring that the products they create follow the rules for design control. This course describes FDA design control regulations by providing basic information about the key procedures followed during the design and development of a product. Topics in this course include: Design and Development Plan, Design Input, Design Output, Design Review, Verification, Validation, Design Transfer, and Change Control. The design plan requires documentation of training, planning validation, design transfer and changes, formal review, a design history file, and human factors. After completing this course, learners will be able to recognize the purpose and scope of design control regulations and will also be able to identify the eight main aspects of design control and how they affect medical device manufacturers.

**Format:** eLearning - SCORM, eLearning - EduFlex  
**Partners:** FDA  
**Libraries:** Medical Device GMPs, Quality Assurance  
**Functional Areas:** Quality Assurance

Destruction and Reconditioning

This course discusses procedures and methods for destroying, reconditioning, and/or denaturing products that are in violation of the FD&C Act. Topics in this course include: Seized Articles, Detained Products, Voluntary Correction, Procedures, and Damage. After completing this course, learners will be able to identify the circumstances and procedures under which articles may be destroyed or reconditioned.

**Format:** eLearning - EduFlex, eLearning - SCORM  
**Partners:** FDA  
**Libraries:** FDA Inspections and Enforcement  
**Functional Areas:** FDA Inspection Readiness

Detecting and Preventing Fraud

This course will identify what constitutes fraud, how to recognize and report potential or actual fraud, and when and how you should report it. After completing this course, you will also be able to recognize internal fraud, computer fraud, social engineering, and money laundering.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM  
**Libraries:** Ethics & Corporate Responsibility  
**Functional Areas:** Corporate Ethics  
**Content Bundles:** Corporate Compliance - Plan Sponsors, Corporate Compliance - General Industry

Dietary Supplements -- cGMP Requirements for Quality Control

This course provides information about regulatory requirements for Dietary Supplement manufacturers, holders, packagers and labelers during Quality Control operations. Topics in this course include: Laboratory Operations, Material Reviews, Returned Products, Packaging and Labeling, and Records. After completing this course, learners will be able to identify regulatory requirements for Quality Control operations, including material reviews and dispositions.

**Format:** eLearning - SCORM, eLearning - EduFlex  
**Libraries:** Dietary Supplements GMPs  
**Functional Areas:** Dietary Supplement GMPs  
**Content Bundles:** cGMPs for Dietary Supplements
Dietary Supplements -- cGMPS for Manufacturing Plants and Equipment
The Final Rule (21 CFR Part 111) defines the current Good Manufacturing Practices (cGMPs) for the Dietary Supplement industry, including specific requirements for facilities and equipment. This course outlines current FDA requirements for facilities that manufacture, package, label, hold, and distribute dietary supplements. Topics in this course include: Physical Plant, Plant Design, Equipment and Utensils, and Records. After completing this course, learners will be able to identify FDA requirements for manufacturing plants and equipment that manufactures dietary supplements.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: Dietary Supplements GMPs

Content Bundles: cGMPS for Dietary Supplements

Dietary Supplements -- Introduction to Part 111 cGMPS
The popularity of dietary supplements and the size of the global industry are increasing rapidly, and product safety has grown into a main concern. Current good manufacturing practices (cGMPS) for dietary supplements have been issued by FDA to address this concern. Topics in this course include: History, Jurisdiction of cGMP Requirements, Basic Terminology, Basic Requirements of the Final Rule, and Personnel Requirements. After completing this course, learners will be able to recognize the origin and scope of cGMPS for dietary supplements. Learners will also be able to identify the purpose of general provisions and personnel subparts, as well as the 16 basic subparts of the 21 CFR Part 111 Final Rule. This course is the second in a series of courses on dietary supplement regulations.


Libraries: Dietary Supplements GMPs

Content Bundles: cGMPS for Dietary Supplements

Dietary Supplements -- Packaging, Labeling, Holding, and Distribution
This course discusses the requirements for dietary supplement product packaging, labeling, holding, and distribution.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Dietary Supplements GMPs

Content Bundles: cGMPS for Dietary Supplements

Dietary Supplements -- Production and Process Control System for Manufacturing Operations
This course is designed to help learners understand and recognize the principles and practices of process control and the role they play in ensuring quality dietary supplement product manufacturing. Topics in this course include: Basic Requirements, Specifications, Contamination, Samples, Evaluation, Testing, Rejections, and Documentation. After completing this course, learners will be able to identify the cGMP process control requirements for manufacturing operations, including sanitation, contamination, rejected products, specifications, in-process adjustments, reserve sampling, and records.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Dietary Supplements GMPs

Content Bundles: cGMPS for Dietary Supplements
Dietary Supplements -- Requirements for Records and Recordkeeping

This course explains how GMP records and associated procedures remain effective and essential elements of maintaining product quality. Topics in this course include: Master Manufacturing Records, Batch Records, Best Practices, Record Retention, and 21 CFR Part 11. After completing this course, learners will be able to recognize the importance of the Master Manufacturing Record (MMR) and Batch Production Records.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Dietary Supplements
- GMPs

Functional Areas:  
- Dietary Supplement
- GMPs

Content Bundles:  
- cGMPs for Dietary Supplements

Discrimination and Harassment Free Workplace

Each of us is responsible for our working environment. Every employee needs to understand the kind of behavior that fosters a positive and productive climate and the unacceptable behavior, such as discrimination and harassment which can negatively affect our workplace. This course addresses the laws and our company's policies related to discrimination, harassment, and diversity, and why they are important. Topics in this course include: Importance, Laws and Policies, Harassment, and Reporting Complaints. After completing this course, learners will be able to recognize how diversity is important to our company's success, the laws and policies that define discrimination and harassment, acceptable and unacceptable behavior, and the proper response to situations of discrimination and harassment.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning -- SCORM

Libraries:  
- Ethics & Corporate Responsibility

Functional Areas:  
- Harassment Topics

Ditch Witch® Pipe Locators

Ditch Witch® Pipe Locators discusses the control features and functions of the Ditch Witch® Pipe Locator receiver and transmitter, the specific operation and line locating methods, and the abnormal operating conditions.

Format:

Libraries:  
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:  
- Midstream Topics

Diversity in the Workplace

The increasing diversity of today's workforce means that employees and supervisors are part of a dynamic and ever-changing environment. This course explains how culture influences values, assumptions, thought processes, and work relationships. Topics in this course include Importance, Change, Laws, and Stereotypes. After completing this course, learners will be able to recognize the changing work environment and identify how to improve their working relationships with people from different backgrounds.


Libraries:  
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:  
- HR Compliance

Content Bundles:  
- HR Compliance
Documenting the Drug Development Process — ICH Q8(R2)

FDA issued the International Conference on Harmonization (ICH) guidance Q8(R2) Pharmaceutical Development. This guidance addresses documenting the drug development process via the Common Technical Document (CTD). Topics in this course include: CTD, Pharmaceutical Development, Drug Components, Drug Product, Manufacturing Process, Container Closure System, and Microbial Attributes. After completing this course, learners will be able to recognize the FDA guidance on pharmaceutical development and be able to identify how it can be used to design and manufacture safe and effective pharmaceutical or biological products that are of consistent quality.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Global Regulatory
- ICH: Quality Management

**Documenting Validation Activities**

The process of validation in FDA-regulated industry is important to gain FDA acceptance. The key to successful validation is the understanding that validation must be documented. This course illustrates the process of documenting validation activities for FDA acceptance. Topics in this course include: Validation, Documents, Equipment, Materials, Process, and People. After completing this course, learners will be able to recognize FDA’s definition of validation and identify the required components of the validation process.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Partners:** FDA

**Libraries:**
- Medical Device GMPs
- Pharmaceutical GMPs

**Functional Areas:**
- Design Controls
- Computer Systems Validation
- QC Laboratories

**Content Bundles:**
- Computer Systems Validation

**Doing Business with the Government**

This 30-minute training module is designed to help you understand how laws and company policies are applicable to your job. This training applies to all employees, even if you are not directly involved in U.S. government contracts.

**Format:**

**Libraries:**
- Ethics & Corporate Responsibility

**Functional Areas:**
- Ethics Basics

**Doing the Right Thing for Customers and Business Partners**

Businesses must be able to demonstrate that they can run their business with integrity and keep their promises. This course explores how to build strong relationships with our customers and business partners through trust, quality and service, privacy protection, and fair treatment. Topics in this course include: Earning Trust, Quality and Service, Protecting Privacy, and Fair Treatment. After completing this course, learners will be able to recognize how to build strong relationships with our customers and business partners.

**Format:** eLearning - SCORM, eLearning - EduFlex

**Libraries:**
- Ethics & Corporate Responsibility

**Functional Areas:**
- Corporate Ethics
Doing the Right Thing: Anti-bribery

This course provides basic training on complying with laws prohibiting bribery, including the US Foreign Corrupt Practices Act (FCPA). Because of the special circumstances facing employees in the healthcare field, this course is focused on issues faced in interactions with healthcare professionals as well as government officials. Topics in this course include: Legal Foundation, Laws, and FCPA in Action. After completing this course, learners will be able to identify and navigate situations that may be perceived as bribery. Learners will also be able to recognize requirements of the FCPA.


Libraries: Ethics & Corporate Responsibility

Functional Areas: Corporate Ethics

Dos and Don'ts of Aseptic Environments

This course introduces best practices for aseptic technique and behavior for use with conventional cleanroom aseptic processing. Topics in this course include: Dos and Don'ts (including Personnel Requirements, Gowning and Gloves, Cleanroom Integrity, Behavior, Critical Area Interactions, and Culture). After completing this course, learners will be able to recognize best practice aseptic behaviors and techniques as well as specific examples of what to do and what not to do in the cleanroom.


Libraries: Not specified

Functional Areas: Aseptic Processing

Languages Available: German (Aseptic07), French (European) (Aseptic07), Spanish (Spain) (Aseptic07)

DOT Alcohol Awareness

DOT Alcohol Awareness addresses workplace substance abuse, DOT-regulated alcohol abuse policies, job performance, crisis situations, alcohol testing requirements, and the roles and responsibilities of supervisors.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

DOT Drug Awareness


Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics
DOT Employee Drug and Alcohol Awareness

Drug and alcohol problems in the workplace cost US employers billions of dollars annually due to sick leave, absenteeism, lost productivity, injuries, fatalities, healthcare costs, legal liabilities, and workers' compensation costs. This course discusses the Department of Transportation (DOT) controlled substances and alcohol use and testing regulations that employers in the transportation industry must follow. Topics in this course include: Depressants, Stimulants, Hallucinogens, Consequences, and Workplace Resources. After completing this course, learners will be able to recognize the different forms of alcohol and drugs, the signs and symptoms of drug and alcohol use and abuse, and the components of an employee substance abuse program.

Format: eLearning - HiP2

Libraries: Environmental Health and Safety

Functional Areas: Drug and Alcohol Training

DOT Hazardous Materials Training -- Carrier Requirements (Air)

The Department of Transportation (DOT) regulates the training of employees involved in commercial transportation of hazardous materials (HAZMAT). This course provides information about the requirements and regulations that must be followed during transportation of HAZMAT by air. Topics in this course include: Responsibilities, Quantity Limitations, Packaging, Placement, Exceptions, Documentation, and National Response Center (NRC). After completing this course, learners will be able to recognize the basic air carrier requirements for transporting HAZMAT.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Environmental Health and Safety

Functional Areas: Hazardous Materials

DOT Hazardous Materials Training -- Carrier Requirements (Highway)

The Department of Transportation (DOT) regulates the training of employees involved in commercial transportation of hazardous materials (HAZMAT). This includes modal requirements for shippers and carriers who transport HAZMAT over highways. Topics in this course include: Motor Carrier, Regulations, Shipping Papers, National Response Center (NRC), Loading and Unloading, Segregation Table, Special Requirements, and Disabled Vehicles. After completing this course, learners will be able to recognize the general motor carrier requirements for HAZMAT shipments. Learners should be familiar with the Code of Federal Regulations and be able to locate parts, subparts, sections, and references within the Hazardous Materials Regulations (HMR), Parts 171-180. Supervisors may require learners to take other courses in this series pertaining to their job duties.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: Environmental Health and Safety

Functional Areas: Hazardous Materials

DOT Hazardous Materials Training -- Carrier Requirements (Rail)

The Department of Transportation (DOT) requires the training of employees involved in commercial transportation of hazardous materials (HAZMAT). This includes training in the rail carrier requirements for those who ship HAZMAT by trains. After completing this course, the student will recognize the basic rail carrier requirements for transporting HAZMAT.

Format: eLearning - HiP2

Libraries: Environmental Health and Safety

Functional Areas: EHS Basics
DOT Hazardous Materials Training -- General Awareness

This course is the first in a series of courses on DOT HAZMAT regulations. Topics in this course include: HAZMAT, Identification, Emergency Response Guidebook, and Security. After completing this course, learners will be able to recognize what types of materials are considered HAZMAT and identify how they are classified. Learners will also recognize the elements of the Emergency Response Guidebook. Learners will be able to identify security programs that are available for the safe transportation of hazardous materials.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Environmental Health and Safety  
- Hazardous Materials

DOT Hazardous Materials Training -- Hazardous Materials Table

In the United States, the Department of Transportation (DOT) requires the training of employees involved in commercial transportation of hazardous materials (HAZMAT). A hazardous material is a substance or material that has been determined by the DOT to pose an unreasonable risk to health, safety, and property when transported in commerce by railcar, aircraft, pipeline, vessel, or motor vehicle. DOT Hazardous Materials Training-General Awareness is a prerequisite for this course. In this course, the student will learn how to use the Hazardous Material Table to safely prepare and transport hazardous materials for shipment.

Format: eLearning - HIP2

Libraries:  
- Environmental Health and Safety  
- Hazardous Materials

DOT Hazardous Materials Training -- Marking and Labeling

In the United States, the Department of Transportation (DOT) regulates the training of employees involved in the commercial transportation of hazardous materials (HAZMAT). This includes training in the proper marking and labeling of HAZMAT shipments. Topics in this course include: Definition, Marking Requirements, Additional Markings, Other Regulated Material, Labeling, and Special Labels. After completing this course, learners will be able to recognize how to use marking and labeling for the safe preparation of HAZMAT. Before taking this course, participants should have completed DOT Hazardous Materials Training — General Awareness and DOT Hazardous Materials Training — Hazardous Materials Table.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Environmental Health and Safety  
- Hazardous Materials

DOT Hazardous Materials Training -- Packaging

The Department of Transportation (DOT) regulates the training of employees involved in commercial transportation of hazardous materials (HAZMAT). This includes training on the proper packaging for HAZMAT shipments. In this course, the student will learn about the purpose and general requirements for HAZMAT packaging, as well as exceptions, exemptions, and special requirements that may apply to particular shipments. DOT Hazardous Materials Training - General Awareness and DOT Hazardous Materials Training - Hazardous Material Table are prerequisites for this course.

Format: eLearning - HIP2

Libraries:  
- Environmental Health and Safety  
- Hazardous Materials
DOT Hazardous Materials Training -- Placarding

In the United States, the Department of Transportation (DOT) requires the training of employees involved in commercial transportation of hazardous materials (HAZMAT). This includes training in the proper placarding of HAZMAT shipments. Placards are usually the first source of information about HAZMAT involved in an accident. After completing this course, you will know how to use and recognize placards in HAZMAT transportation. DOT Hazardous Materials Training - General Awareness and DOT Hazardous Materials Training - Hazardous Materials Table are prerequisites for this course.

Format: eLearning - HIP2
Libraries:  
- Environmental Health and Safety  
- Hazardous Materials

DOT Hazardous Materials Training -- Security Awareness

Anyone who offers, transports, or stores hazardous materials (HAZMAT) should take security awareness training to learn how to increase the security of their HAZMAT shipments. This course explains how to improve personnel, facility, and en route security measures, and identifies security tips for HAZMAT shippers, receivers, and carriers. Topics in this course include: Potential Targets, Security Plan, Personnel Security, Facility Security, and En Route Security. After completing this course, learners will be able to recognize the factors that make a particular target attractive to attackers and identify suspicious behavior.

Format: eLearning - SCORM, eLearning - EduFlex
Libraries:  
- Environmental Health and Safety  
- Hazardous Materials

DOT Hazardous Materials Training -- Shipping Papers

The United States Department of Transportation (DOT) requires the training of employees involved in commercial transportation of hazardous materials (HAZMAT). This includes training in the completion of shipping papers, which provide HAZMAT employees with vital information to initiate protective actions in case of an emergency. Topics in this course include: Preparation and Retention, Basic Shipping Description, Additional Requirements, Emergency Information, Certification, and EPA Requirements for Waste. After completing this course, learners will be able to identify the requirements for shipping papers when preparing a HAZMAT shipment. In order to take this course, learners must be familiar with the DOT Hazardous Materials Table and know how to interpret the information in the table. This information is available in the DOT Hazardous Materials Training - General Awareness and DOT Hazardous Materials Training - Hazardous Materials Table courses.

Format: eLearning - SCORM, eLearning - EduFlex
Libraries:  
- Environmental Health and Safety  
- Hazardous Materials

Dresser Coupled Pipelines

Dresser Coupled Pipelines explains what a Dresser coupling is and how it works, bonding couplings, locating unbonded couplings, factors and conditions that help determine repair procedures, and types of repairs. Abnormal operating conditions (AOCs) that may be encountered while inspecting and repairing Dresser couplings are included, along with possible responses.

Format:
Libraries:  
- DOT Operator Qualification - Oil And Gas Pipeline  
- Midstream Topics
Driver Safety Program (DSP)

Traffic accidents injure and kill thousands of people each year. The majority of these accidents could have been prevented. This course identifies practices related with safe driving. Topics in this course include Becoming a Safer Driver, Vehicle Condition, Aggressive Drivers, Impaired Drivers, and Problems. After completing this course, learners will be able to identify safe driving practices including driving defensively, how to handle aggressive drivers, and what to do in the event of an accident.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: Environmental Health and Safety

Functional Areas: EHS - Driver Safety

Languages Available: Spanish (Latin America), French (Canadian)

Drug Safety & Adverse Event Reporting

This course explains the regulatory requirements in the clinical trial and post-marketing environments, while also describing the international drug safety monitoring efforts. Topics in this course include History, Pre-clinical Safety Data, Sponsor Responsibilities, and Postmarketing Reports. After completing this course, learners will be able to recognize terminology associated with drug safety monitoring during clinical trials, identify sponsor's responsibilities regarding safety reporting, and recognize the importance of drug safety and adverse event reporting.


Libraries: Clinical Pharmaceutical

Functional Areas: GCP - Clinical Management

Content Bundles: Good Clinical Practices (GCP)

Languages Available: Chinese (Simplified), German, Japanese

Edit Group Criteria Enhancement Overview

No description specified

Format: eLearning - EduFlex

Libraries: Not specified

Effective Media Relations

Effective Media Relations addresses how to participate in a media interview at the scene of an emergency; the five "Ws" and the "nine points"; what emergency response officials and the news media should know during a company emergency; providing the media with proper contact information; a spokesperson’s role during pipeline emergencies, including compliance with DOT regulation Title 49 CFR 192.615; and use of pipeline maps and drawings.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Languages Available: Not specified
Effectively Responding to FDA 483s and Warning Letters

No company wants to receive an FDA 483 or Warning Letter for adverse findings after an FDA inspection, but it does happen. This course explains the basic principles of FDA 483s and the use of Warning Letters to provide feedback on compliance concerns. Topics in this course include: FDA 483, Response, Warning Letter, Response Process, and Avoiding Mistakes. After completing this course, learners will be able to describe key aspects of written responses to both FDA 483s and Warning Letters, and recognize the importance of both of these documents.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs
Functional Areas:
- FDA Inspection
- Readiness
Partners: FDA

Languages Available:
- Chinese (Simplified)
- Japanese
- Spanish (Spain)

Electric Arc Welding

Electric Arc Welding examines types of electric arc welding, types and uses of joints, weld defects and prevention, preheating a weld area, electrode selection and storage, welding sequence, pipe beveling and lineup, arc welding techniques, striking the arc, hot and cold welding and cutting, weld positions, field inspections of welds, and safety precautions during electric arc welding.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas:
- Midstream Topics

Electric Valve Actuators

Electric Valve Actuators explains the basic design, design features, operation, inspections, lubrication, and overall maintenance techniques for electric valve actuators. Abnormal operating conditions (AOCs) associated with electric valve actuators are included.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas:
- Midstream Topics

Electrical Insulator Inspections and Testing Casings

Electrical Insulator Inspections and Testing Casings explains the purpose and requirements for pipeline casings, types of casing, coatings, testing casing, electrical insulating devices, and testing insulating devices. Abnormal operating conditions (AOCs) that may be encountered while testing casing and insulating devices are included.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas:
- Midstream Topics

Electrical Safety

Almost every workplace uses electricity as its main source of energy. Working around electricity can cause significant injuries and even death, known as electrocution. It is important that we know how to protect ourselves against electricity. This course discusses basic electrical principles, how to identify potential hazards, and safe work practices. In addition, participants will learn how to respond to an electrical incident in the workplace.

Format: eLearning - SCORM, eLearning - EduFlex
Libraries:
- Environmental Health and Safety
- Hazardous Materials
Function Areas: 
- EHS for Life Science Companies - Basics
Content Bundles:
- EHS for Life Science Companies - Basics
Languages Available:
- Spanish (Spain)
Electrofusion
Electrofusion examines types of plastic pipe used in the electrofusion process, basic principles of electrofusion, the electrofusion process, inspection and testing of fused joints, safety precautions when handling polyethylene pipe, hazards of static electricity, and spark prevention.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

E-Mail and Corporate Communications
E-mail remains the predominant form of communication in the business world, with estimates ranging in excess of 100 billion e-mails sent and received daily. This course illustrates the use of e-mail in the workplace, including several hot-button issues, such as an employee's expectation of privacy, and electronically transmitted computer viruses. Topics in this course include: How E-mail Works, E-mail Use, and Privacy and Security. After completing this course, learners will be able to recognize the consequences of sending or forwarding an inappropriate e-mail attachment or message.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Ethics & Corporate Responsibility

Functional Areas:
- Corporate Ethics

Emergency Plans & Public Contractor Education
Emergency Plans & Public Contractor Education addresses emergency action plans and reviews damage prevention programs including one-call systems, public and contractor education about gas pipelines, and response procedures for pipeline damage from an outside force.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Emergency Preparedness for Healthcare Workers
The primary goal of healthcare facilities is the preservation of life. When emergency situations arise, this goal is compromised, and certain measures must be implemented to deal with unexpected events. There are many types of emergencies that can occur in healthcare facilities. This course covers the different types of emergencies and the general procedures that employees should follow in addition to their site-specific emergency response plans. It should be taken in conjunction with the Fire Safety for Healthcare Workers and Fire Extinguishers courses.

Format: eLearning - HIP2
Libraries:
- Environmental Health and Safety

Functional Areas:
- EHS Basics for Healthcare Workers
Emergency Response Plan for Natural Gas Pipelines

Emergency Response Plan for Natural Gas Pipelines explores the components of respective emergency response plans utilized by the natural gas and liquefied natural gas pipeline industries.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations

This course provides an overview of Postmarketing Adverse Drug Experience (PADE) regulations, guidance, inspectional candidate selection, inspectional techniques, and regulatory actions to enhance the field investigator’s knowledge. Topics in this course include: Reporting, FAERS, Types of ADE Reports, ADE Team, Inspecting, and Compliance. After completing this course, learners will be able to recognize how to perform the inspectional activities necessary to monitor industry’s surveillance, receipt, evaluation, and submission of adverse drug experience information to FDA.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement

Functional Areas:
- FDA Inspection Readiness

Environmental Awareness

Environmental Awareness is designed to make all employees aware of the types of environmental concerns that pipeline operators must address, including regulatory requirements.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Environmental Control and Monitoring

It is important for all personnel involved in the manufacturing of sterile products and medical devices to understand how to maintain the quality of the cleanroom environment through environmental control and monitoring. This course examines regulatory requirements for environmental control and monitoring and how to prevent particulate and microbiological contamination of sterile products and devices. Topics in this course include: Purpose, Control, Monitoring, Documentation, and Prevention. After completing this course, learners will be able to recognize the methods of environmental control and monitoring, and identify how to prevent contamination.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- Maintenance and Facilities
- QC Laboratories

Content Bundles:
- Maintenance and Facilities - Basics
- Basics of Aseptic Processing

Languages Available:
- German (PHDV87)
- French (European) (PHDV87)
- Chinese (Simplified) (PHDV87)
- Japanese (PHDV87)
- Korean (PHDV87)
- Spanish (Spain) (PHDV87)
Environmental Management Systems

Many companies don't know how to implement Environmental Management Systems (EMSs), and those that do are often fearful that the EPA may use results from their implementation against them, resulting in fines, money damages, and adverse publicity. In today's world, that is changing and a company's proactive efforts in doing what is good for the environment can actually result in reduced liability and improved competitiveness in the marketplace. Environmental management and best business practices are now truly interrelated and focused on the integrating environmental management into business goals. After completing this course, the learner will be able to recognize the purpose and elements of an effective Environmental Management System, as well as identify the incentives that the EPA grants companies for implementing them.

Format: eLearning - HIP2

Libraries: Environmental Health and Safety

Functional Areas: Environmental Topics

Environmental Regulation

This course addresses the importance of complying with environmental regulations and introduces many regulations that protect the environment. After completing this course, learners will be able to identify the importance of environmental regulation, recognize laws and regulations that protect the environment, and identify how a facility inspection is conducted.

Format: eLearning - EduServer

Libraries: RETIRED - Energy Operations

Functional Areas: Midstream Topics

EPA Inspections

In a typical year, the federal Environmental Protection Agency (EPA) and state environmental enforcement agencies conduct over 90,000 inspections throughout the United States. These inspections have resulted in millions of dollars in criminal, civil, and administrative penalties. The goal of these inspections is to ensure compliance with laws enacted to protect both the environment and employees from toxic and hazardous waste. In this course, participants will learn the types of EPA inspections, and the criteria used for selecting companies for inspection. They will also receive an overview of the inspection process, and the basic legal rights a company has when an inspector shows up at its front gate. NOTE: This course is NOT designed to provide legal advice. If you need legal advice before, during, or after an EPA inspection, you should seek legal counsel.

Format: eLearning - HIP2

Libraries: Environmental Health and Safety

Functional Areas: Environmental Topics

Ergonomics: Body Mechanics and Fitness

This course discusses the importance of workplace ergonomics and body mechanics in maintaining health and preventing injury while on the job. Topics in this course include: The Back, Protecting Your Back, Ergonomics, Body Mechanics, Strengthening Muscles, and Workplace Fitness. After completing this course, learners will be able to recognize basic body mechanics and ergonomic principles that can prevent injury.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: Environmental Health and Safety

Functional Areas: Workplace Safety

Languages Available: Dutch (EHS33), Spanish (Latin America) (EHS33)
Essentials of an Effective Calibration Program

Injuries, fatalities, or major class action suits filed against the manufacturer can result when products are produced with out-of-calibration equipment. This course identifies the essentials of an effective calibration program. This course contains references to both U.S. and EU regulations. Topics in this course include the four aspects of calibration, calibration standards, regulatory requirements, and calibration procedures. After completing this course, learners will be able to recognize the reasons for calibration and the requirements and standards of effective calibration programs.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: • Medical Device GMPs  • Pharmaceutical GMPs
Functional Areas: • Maintenance and Facilities
Partners: FDA
Content Bundles: • Maintenance and Facilities - Basics

Languages Available: Chinese (Simplified)  Japanese  Korean  Spanish (Spain)

Ethical Review Boards

This course addresses the role, responsibilities, and regulatory requirements of Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) in protecting the rights and welfare of human research subjects. Topics in this course include: Development, Membership/Procedures, Review and Approval, Post-Approval Responsibilities, Vulnerable Subjects, Noncompliance, and Compliance Resources. After completing this course, learners will be able to recognize their obligations in relation to the IRB/IEC and the policies and procedures that were developed to protect and safeguard research subjects.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: • Clinical: Medical Device  • Clinical: Pharmaceutical
Functional Areas: • GCP - Clinical Management

Ethical Third Party Sales and Marketing Intermediary (“SMI”) Relationships

This course explores third party sales and marketing intermediary relationships. It discusses the key regulatory risks associated with sales and marketing with third parties, depicts how an effective compliance program can assist a company in mitigating regulatory risks, and describes essential elements of an effective compliance program.

Format: eLearning - Magazine
Libraries: • Medical Device - Sales & Marketing  • Medical Device - Sales & Marketing
Functional Areas: • Corporate Compliance Basics  • Corporate Ethics  • Medical Device Sales Compliance  • Pharmaceutical Sales Compliance

Ethics and Compliance

Ethics and Compliance examines ethics and compliance as they apply to a Code of Conduct and company policy for all employees of a pipeline company, including senior management and the board of directors.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: • Midstream Topics
Ethics as the Foundation to Clinical Research

All clinical research personnel confront ethical decisions. This course reviews the principles and methods that exist to ensure that the rights and welfare of human subjects are protected. Topics in this course include: Ethical Documents, Decision-Making Process, Emerging Trends, and Considering the Ethical Dilemma. After completing this course, learners will be able to recognize the ethical components of historical clinical research guidelines, the definition of clinical equipoise and its importance in clinical trials, and one systematic approach to ethical decision-making.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical
Functional Areas:
- GCP - Clinical Management

EU Directives and Inspection Readiness

The EU has strict requirements for the manufacture and supply of medicinal products, which are defined in EU directives and GMP guides. To confirm that these requirements are being complied with, manufacturers and suppliers are regularly inspected. If significant deficiencies are identified during inspections, the company may face sanctions and could even be barred from supplying product. Upon completion of this course, you will be able to identify the regulatory background regarding EU inspections, the expectations inspectors may have, and how to prepare for inspections.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs
Functional Areas:
- EU Regulations
- FDA Inspection Readiness
Content Bundles:
- GMP Inspection Readiness

EU In Vitro Diagnostic Regulations (IVDR)

This course describes information about the compliance of the in vitro diagnostic medical devices in accordance with the European In Vitro Diagnostic Medical Device Regulations (IVDR). Topics in this course include: Definitions, Regulatory Requirements, Conformity Assessments and Performance Studies, and EU Portal and Surveillance. After completing this course, learners will be able to recognize essential requirements and harmonized standards for in vitro diagnostic medical devices.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Medical Device GMPs
- Global Regulatory
Functional Areas:
- EU Market Access
- EU Regulations
- EU MDD

EU Medical Device Regulation (MDR)

This course describes basic information concerning the European Medical Device Regulation and the CE marking of medical devices. Topics in this course include: History, Definitions, Approach, Quality System, and General Classifications and Rules. After completing this course, learners will be able to identify the basic components of the EU Medical Device Regulation (MDR).

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Medical Device GMPs
- Global Regulatory
Functional Areas:
- EU Market Access
- EU Regulations
- EU MDD
European Union Clinical Trials Directive

The European Union (EU) Clinical Trials Regulation covers clinical trials in the EU and sets forth requirements of investigators, sponsors, EU Member States’ Competent Authorities, and others responsible for clinical trial regulation. Topics in this course include: Requirements and Responsibilities, Overall Authorization, Modifications and Amendments, IMPs, and Adverse Events. After completing this course, learners will be able to identify the principal elements of the EU Clinical Trials and Good Clinical Practice Directives.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Languages Available: French (European), German, Spanish (Spain)

Libraries: Clinical: Medical Device, Clinical: Pharmaceutical

Functional Areas: GCP - Clinical Management

European Union GMP Requirements

If you are involved with the manufacture of medicinal products you must comply with Good Manufacturing Practice (GMP) requirements. This course explains the European Union's (EU) GMP regulations and guidelines. Topics in this course include: Pharmaceutical Quality Systems, Staff, Premises and Equipment, Documentation, Production, Quality Control Department, and Controls. After completing this course, learners will be able to identify the EU's basic GMP regulations and recognize how to comply with these requirements.

Format: eLearning - EduFlex, eLearning - SCORM

Languages Available: Spanish (Spain), French (European), German, Chinese (Simplified), Japanese

Libraries: Pharmaceutical GMPs, Functional Areas: EU Regulations, GMP Pharmaceuticals - EU Regulations, Pharmaceutical GMPs - Basics

European Union GMP Requirements for Computerised Systems

This course introduces the European Union's GMP requirements for computerised systems that are associated with the manufacture of medicinal products. Reference is also made to FDA expectations. This course covers requirements that govern the use of computerised systems as specified in regulations and guidance documents issued by the European Union.

Format: eLearning - EduFlex, eLearning - SCORM

Languages Available: German, French (European), Spanish (Spain)

Libraries: Medical Device GMPs, Pharmaceutical GMPs

Functional Areas: GMP - EU Regulations

European Union Good Distribution Practices for Medicinal Products

This course describes the Good Distribution Practices required by the European Union (EU). The EU’s recommended practices are similar to requirements in the US and many other countries. The controls to maintain the quality and integrity of medicinal products as they are distributed from manufacturer to patient are explained in this course. Because modern supply chains are often complex, the responsibilities of all organisations involved with wholesale activities — including storage, transport, purchase, and supply — are detailed. The controls required to prevent falsified or fake products entering the supply chain are also addressed.

Format: eLearning - EduFlex, eLearning - SCORM

Languages Available: German, French (European), Spanish (Spain)

Libraries: Pharmaceutical GMPs, Global Regulatory

Functional Areas: GMP Pharmaceuticals - EU Regulations
Evidence and Proof

FDA takes action based on information collected and developed by investigational and analytical personnel. FDA's ability to perform its function is based on the quality and care used in collecting and preserving information. Information is evidence; obtaining it properly is a vital portion of FDA's law enforcement work. This course explores forms of evidence and proof. Topics in this course include: Physical Evidence, Photographic Evidence, Written Evidence, Testimony, Elements of Proof, and FDA Actions. After completing this course, learners will be able to recognize the processes involved in gathering evidence and proof, and identify the circumstances under which both can be used.

Format: eLearning - EduFlex, eLearning - SCORM
Partners: FDA

Excavations

Excavations are performed thousands of times a day across the United States. Unfortunately, thousands of people are also killed by cave-ins and accidents in excavations each year. These incidents can happen in seconds, virtually unnoticed. This course presents information on how to perform excavations properly to avoid the special hazards related to this type of work. In this course, participants will learn information on excavations including the types of hazards involved, the role of a competent person, and the personal protective equipment required. The causes of cave-ins and means of preventing them will also be examined.

Format: eLearning - HIP2

Facility Response Plan for Hazardous Liquids Pipelines

Facility Response Plan for Hazardous Liquids Pipelines is an overview course about the type of facility response plan utilized in the hazardous liquids pipeline industry.

Format:

Failure Investigations for Medical Device Manufacturers

Handling medical device failures can be significant in a company's ability to maintain a state of control in operations and prevent future failures. This course will explore what a failure is, the regulatory and practical aspects of investigations, and the elements that make these investigations effective. Topics in this course include: Product Failure, Investigations, Root Cause, CAPA, Follow-up, and Documentation. After completing this course, learners should be able to recognize the basic definition of failures, identify when a failure investigation should occur, and the documentation required.

Partners: FDA

Languages Available:
Chinese (Simplified) (DEV45)
Japanese (DEV45)
Korean (DEV45)
Failure Investigations for Pharmaceutical Manufacturers

An effective system for conducting failure investigations can provide a means for preventing recurrences. This course will familiarize the learner with GMP regulations regarding failure investigations and the key components of a good investigation. Topics include: Failures, Root Cause, Corrective Actions, Follow-Up, and Investigation Reports. After completing this course, you will be able to identify the failure investigation process. You will be able to recognize how GMP regulations address failure investigations and the key components of a good investigation. You will also be able to identify how to determine the root cause of a failure and recognize the importance of corrective actions and follow-ups to failure investigations.

Languages Available:
- German (PHA59)
- French (European) (PHA59)
- Japanese (PHA59)
- Spanish (Spain) (PHA59)


Libraries:
- Pharmaceutical GMPs

Functional Areas:
- Pharmaceutical GMPs
  - Root Cause Analysis

Fair Labor Standards Act (FLSA) and Equal Pay Act (EPA)

The Fair Labor Standards Act (FLSA) is a federal law that establishes minimum wage, overtime pay, recordkeeping, and youth employment standards. The Equal Pay Act (EPA) is a federal law that requires men and women in the same workplace to receive equal pay for equal work.

This course provides an overview of the FLSA and EPA with a concentration on employer concerns. It also covers important distinctions between exempt and non-exempt employees and between employees and independent contractors. Topics in this course include: FLSA, Minimum Wage, Overtime, Exempt Employees, Contractors, Compensatory Time, Child Labor, Nursing Mothers, and Equal Pay Act (EPA). After completing this course, learners will be able to recognize the significant aspects and exemptions of both the FLSA and EPA.

Languages Available:
- Spanish (Latin America) (LAV06)

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:
- Corporate Compliance Basics

Fall Protection

Falls are a leading cause of accidents on construction sites, killing hundreds and disabling hundreds of thousands of workers each year. This course presents information about the hazards of falls, and specific requirements for fall protection. Topics in this course include: Types of Falls, Fall Protection, Fall Prevention, Fall Control, and System Considerations. After completing this course, learners will be able to recognize the dangers of all falls, the greater dangers of falls from height, and fall protection requirements that apply to any work done at a high elevation.

Languages Available:
- Spanish (Latin America) (LAV06)

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Environmental Health and Safety

Functional Areas:
- EHS Basics

Family and Medical Leave Act (FMLA)

Managers and supervisors in the workplace must fully understand the federal Family and Medical Leave Act (FMLA). This course explains who is covered by the FMLA and what leave and other benefits must be provided to eligible employees. Topics in this course include: Eligibility, Types of Leave, Conditions and Coverage, Notices, Job Restoration, Non Discrimination/No Retaliation Policy. After completing this course, learners will be able to understand the provisions of the FMLA.

Languages Available:
- Spanish (Latin America) (LAV06)


Libraries:
- HR Compliance & Risk Management

Functional Areas:
- HR Compliance

Content Bundles:
- HR Compliance
FDA 483s: Inspectional Observations

This course is designed to familiarize FDA staff with the important aspects of the FDA 483. Topics in this course include: FDA 483, Objectionable Conditions, Reportable Conditions, Essentials, and Annotation. After completing this course, you will recognize the purpose of issuing an FDA 483. You will be able to identify what kinds of inspectional observations are included on an FDA 483, when that form is issued to the inspected firm, and how to annotate it during the discussion with management.

Format: eLearning - EduFlex, eLearning - SCORM
Languages Available: Chinese (Simplified)
Partners: FDA
Libraries: FDA Inspections and Enforcement
Functional Areas: FDA Inspection Readiness

FDA Establishment Inspection (EI)

FDA performs approximately 15,000 establishment inspections (EIs) per year. Topics in this course include: FDA Authority, Preparation, Initiating Inspection, Refusals, Observation, Evidence, and Concluding an Inspection. After completing this course, learners will be able to recognize the procedures to prepare for, conduct, and conclude inspections.

Format: eLearning - EduFlex, eLearning - SCORM
Languages Available: Chinese (Simplified)
Partners: FDA
Libraries: FDA Inspections and Enforcement
Functional Areas: FDA Inspection Readiness

FDA Establishment Inspection Report Writing

Establishment inspection reports (EIRs) are written reports that create a record of an inspection of a regulated firm. This course illustrates the purpose of the establishment inspection report (EIR), and what should be included in an EIR. Topics in this course include: FDA Required Standards, Parts of an EIR, Readability, and Additional Formats. After completing this course, learners will be able to identify the purpose and multiple uses of the EIR, recognize the items to be included in the EIR, recognize ways to make the report more readable, and identify multiple formats of the EIR.

Format: eLearning - EduFlex, eLearning - SCORM
Languages Available: Chinese (Simplified)
Partners: FDA
Libraries: FDA Inspections and Enforcement
Functional Areas: FDA Inspection Readiness

FDA Good Guidance Practices (GGPs)

This course on FDA Good Guidance Practices (GGPs) explains which Agency documents are considered guidance documents. It also explains why we have GGPs, their legal effect, how they are developed, and GGP implementation. Topics in this course include: Purpose and Scope, Implementation, Issuing Guidance, and Legal Effects. After completing this course, learners will be able to describe the history, development, issuance, and use of Agency guidance. Learners will also be able to recognize how and why GGPs were established.

Format: eLearning - EduFlex, eLearning - SCORM
Languages Available: French (European)
Partners: FDA
Libraries: FDA Inspections and Enforcement
Functional Areas: FDA Inspection Readiness
**FDA Training and Qualification Requirements**

Effective personnel training and qualification can produce a competent workforce, which can lead to a reduction of errors/deviations, customer complaints, regulatory risk, and operational costs. This course addresses the measures required to stay in compliance with FDA regulations, and the requirements needed to implement an effective training and qualification program. This course also discusses specific responsibilities of personnel, records that need to be maintained, and how to measure training and qualification. Topics in this course include: Responsibilities, System Requirements, Training Specifics, Qualification Specifics, and Metrics. After completing this course, learners will be able to identify FDA's requirements for personnel training and qualification, responsibilities of personnel, and how to measure training and qualification.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Libraries:**
- Medical Device GMPs
- Pharmaceutical GMPs

**Functional Areas:**
- Pharmaceutical GMPs
  - Training

**Languages Available:**
- Chinese (Simplified) (PHA67)
- Japanese (PHA67)
- Korean (PHA67)

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**Field Examinations**

Field examinations help to ensure the safety, purity, and compliance of products released for public use. For imported products, field exams help to determine legal admissibility. This course is designed to familiarize individuals with the "what, why, and when" of conducting examinations of products while performing inspections, sample collections, or surveillance activities. Topics in this course include: Scope, Indicators, Equipment, and Conduct. After completing this course, learners will be able to recognize the basics of field examinations. In addition, learners will also be able to identify the types of field examinations, the equipment commonly used during field examinations, and ways to conduct these examinations.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- FDA Inspections and Enforcement

**Functional Areas:**
- FDA Inspection Readiness

**Partners:** FDA

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**Financial Disclosure by Clinical Investigators**

This course provides a summary of Title 21 of the Code of Federal Regulations (CFR) Part 54 entitled "Financial Disclosure by Clinical Investigators." This course discusses which financial arrangements must be disclosed, as well as investigator and sponsor responsibilities when disclosing financial information. Topics in this course include: Requirements, Responsibilities, and FDA Evaluation. After completing this course, learners will be able to identify the types of financial arrangements that must be disclosed and recognize how FDA evaluates the submitted financial information and the actions they may take if it is inadequate.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**
- Clinical: Medical Device
- Clinical: Pharmaceutical

**Functional Areas:**
- GCP - Clinical Management

**Content Bundles:**
- Good Clinical Practices (GCP)

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**Fire Extinguishers**

Employees in the workplace need to be able to appropriately respond to a fire emergency. This course explains how fires are caused and how workers should respond to a fire. Topics in this course include: Causes, Response, Classification, and Extinguisher Use. After completing this course, learners will be able to identify the basic properties of fire and fire extinguishers and recognize how to respond to a fire emergency.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Environmental Health and Safety

**Functional Areas:**
- EHS - Fire Prevention

**Content Bundles:**
- EHS for Life Science Companies - Basics

**Languages Available:**
- Spanish (Latin America)
- German
- French (European)
- Chinese (Simplified)
- Japanese
Fire Prevention

Even small fires can cause injury and death, interrupt production, and destroy equipment and facilities. The primary goal of this course is to increase awareness and understanding so that employees can reduce or eliminate fire hazards in the workplace. Topics in this course include: Components and Classification, Fuel Sources, Oxygen, Heat Sources, Extinguishing Fires, and Fire Prevention Plan. After completing this course, learners will be able to recognize the different types of fires, their causes, and methods to prevent fires in the workplace.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:
- Environmental Health and Safety
- EHS - Fire Prevention

Fire Safety for Healthcare Workers

Fire safety in healthcare facilities is especially crucial because employees are not just keeping themselves safe. They’re responsible for the safety of patients as well. This course identifies measures specifically designed to keep workers and patients in a healthcare facility safe. Topics in this course include: Ingredients, Fire Classes, Safe Practices, Regulatory Requirements, and Response and Plan. After completing this course, learners will be able to recognize the sources of heat, oxygen, and fuel that can help start a fire.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:
- Environmental Health and Safety
- EHS - Fire Prevention
- Healthcare: General

First Aid

Other employees can be the first line of defense in giving assistance to injured people when an emergency arises at the workplace. This course will prepare participants to perform emergency care, which can be given before emergency medical services (EMS) arrive. Participants will learn the initial actions they should take, as well as the proper first aid treatment for heart attacks, bleeding, shock, burns, an object in someone’s eye, nosebleeds, and heat and cold emergencies.

Format: eLearning - Magazine

Libraries:
- Environmental Health and Safety
- Workplace Safety

Flammable and Combustible Liquids

Petroleum is a flammable liquid, and practically everyone uses it to fuel their cars. But flammable and combustible liquids are dangerous. Something as simple as whether or not you promptly put a liquid in a flammable liquid storage cabinet can be a matter of life or death. This course covers risks associated with flammable and combustible liquids, and general safety procedures such as proper storage and use. Ideal learners are all employees.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline
Food and Drug Law: Criminal Acts Violations

This course will describe several felony criminal statutes available for use by FDA that are not part of Title 21 of the USC. These are statutes that have been used in the past and are most likely to be used for felony violations associated with Title 21 criminal prosecutions. Topics in this course include: Definition, False Statements, Mail and Wire Fraud, Justice Obstruction, Conspiracy, Aiding and Abetting, and Intent. After completing this course, learners will be able to recognize what constitutes as criminal felony behavior and the means by which FDA proves criminal intent. Learners will also be able to identify specific elements of proof for the statutes covered in this course.

This is the fourth course in a series of courses on FDA’s Food and Drug Law.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: 
- FDA Inspections and Enforcement

Functional Areas: 
- Food and Drug Law

Food and Drug Law: FDA Jurisdictions

This course introduces the legal jurisdiction of FDA and the responsibilities and limits assigned by Congress to FDA. Topics in this course include: Jurisdiction History, Responsibilities, Foods, Drugs, Devices, Cosmetics, and Jurisdiction Limits. After completing this course, learners will be able to recognize the scope and limits of FDA jurisdiction. Learners will also recognize how products are regulated within the different industries.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: 
- FDA Inspections and Enforcement

Functional Areas: 
- Food and Drug Law

Food and Drug Law: Imports and Exports

This course is a general introduction to Chapter 8 of the Federal Food, Drug, and Cosmetic (FD&C) Act, which addresses Imports and Exports. Topics in this course include: Imports, Exports, Primary Agencies, Other Agencies, Importers, Samples, Violative Samples, and Preventing Violations. After completing this course, learners will be able to recognize the definition of imports and exports and recognize various imported and exported products. Learners will also be able to identify the roles agencies play in the import and export of FDA regulated products, as well as non-government parties involved in the import process. Finally, learners will be able to recognize how FDA determines that a sample is in violation of the FD&C Act and prevents violative products from entering the US. Before taking this course, employees should have completed FDA01 — Food and Drug Law: FDA Jurisdictions and FDA03 — Food and Drug Law: Prohibited Actions in the online “Food and Drug Law” series. This course is not intended to provide detailed legal guidance to any party.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: 
- FDA Inspections and Enforcement

Functional Areas: 
- Food and Drug Law
Food and Drug Law: Judicial Actions

This course will address the types of judicial actions, both criminal and civil, that are available to FDA as part of its law enforcement armory in the event it encounters suspected violations of the Food, Drug, and Cosmetic (FD&C) Act. Topics in this course include: Judicial System, Law Enforcement, The Laws, Criminal Penalties, and Civil Penalties. After completing this course, learners will be able to identify how FDA is empowered to take judicial action, identify the laws enforced by FDA, identify the entities that enforce federal law, and recognize what criminal and civil penalties may be imposed for violations of the FD&C Act and related laws. Prerequisites for this course are FDA01 — Food and Drug Law: FDA Jurisdictions and FDA02 — Food and Drug Law: Prohibited Actions.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: FDA Inspections and Enforcement

Functional Areas: Food and Drug Law

Partners: FDA

Food and Drug Law: Prohibited Actions

The FD&C Act specifically describes what actions are violations and who will be held accountable for those actions. This course discusses prohibited actions under that law. Topics in this course include: Common Violations, Consequences, Responsibility, and Defining Cases. After completing this course, learners will be able to recognize the specific acts that are prohibited under the FD&C Act. Learners will also be able to identify the most commonly violated acts and recognize how FDA determines who is responsible. Finally, learners will be able to identify major cases that establish consequences for violating prohibited acts, and recognize what these consequences may be.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: FDA Inspections and Enforcement

Functional Areas: Food and Drug Law

Partners: FDA

Foreign Corrupt Practices Act (FCPA)

This course explores the Foreign Corrupt Practices Act (FCPA) and anti-bribery. It discusses the laws, regulations, and policies associated with anti-bribery and anti-corruption.


Libraries: Ethics & Corporate Responsibility

Functional Areas: Corporate Ethics

Content Bundles: Corporate Compliance - General Industry

Languages Available:
- German (ETHICS16)
- Italian (ETHICS16)
- French (European) (ETHICS16)
- Dutch (ETHICS16)
- Japanese (ETHICS16)
- Chinese (Traditional) (ETHICS16)
- Portuguese (Brazil) (ETHICS16)
- Spanish (Spain) (ETHICS16)
- Turkish (ETHICS16)

Forklift Safety

Forklift operators must adhere to strict operating and inspection guidelines. This course describes safe operation techniques and inspection methods applicable to forklifts, tractors, platform lift trucks, and motorized hand trucks, as well as other specialized industrial trucks powered by liquid petroleum (LP), electricity, or gasoline. Topics in this course include: Controls and Instrumentation, Load Capacity, Stability, Inspection, Safety Procedures, and Training. After completing this course, learners will be able to recognize how to safely operate a forklift.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Environmental Health and Safety

Functional Areas: Workplace Safety

Languages Available:
- Spanish (Latin America)
Formaldehyde

Formaldehyde is a chemical used widely in manufacturing, agriculture, and various other industries. Exposure to as little as 25 parts per million can cause serious injury or death. Participants in this course will learn the hazards of formaldehyde, the location of resources for information on formaldehyde, measures to protect against exposure, and the requirements for medical surveillance.

Format: eLearning - HIP2

Libraries:  
- Environmental Health and Safety

Functional Areas:
- EHS Basics

Fraud and Abuse Awareness

Fighting fraud and abuse within a health plan is important, and associates are valuable assets in anti-fraud efforts. This course describes how an increased awareness of fraud and abuse will help in the prevention and detection of fraud and abuse. Topics in this course include: The Fight against Fraud, Problem Providers, Suspect Subscribers, Victims, Fighting Back, and Responding. After completing this course, learners will be able to identify how to report common types of fraud and abuse. In addition, learners will be able to recognize the negative effects fraud and abuse have on business and our customers.


Libraries:  
- Healthcare: General

Functional Areas:
- Healthcare: Fraud and Abuse

Fundamentals of Electricity

Fundamentals of Electricity addresses basic properties of electricity, circuits, and safety device components; Ohm’s law; measuring voltage, current, and resistance; types of switches and relays; common electrical symbols and their use in wiring and line diagrams; inductance and capacitance; waveform properties and phase relationships; and transformers.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Gas Control

Gas Control examines major gas control terminology, flow rate and pressure, SCADA systems, compressor operation basics, emergency response, and overpressure protection for pipelines carrying high-pressure gas.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
Gate Valve Maintenance

Gate Valve Maintenance explains how a gate valve operates, along with many of the different design features and their purpose. It also discusses proper cleaning, lubricating, and maintenance techniques that are unique to gate valve maintenance. Common abnormal operating conditions (AOCs) that may be encountered while inspecting or maintaining valves are identified, including proper reactions.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

GCP/ICH Obligations of Sponsors and Monitors

This course describes sponsor and monitor requirements and responsibilities for the conduct of clinical trials in support of new drug and biologics applications. Topics in this course include: Sponsor’s Role, Research Team, Investigators, Prestudy Site Visit (PSV), Other Visits, and Monitoring Activities. After completing this course, learners will be able to recognize the roles and responsibilities of sponsors and monitors during clinical trials.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- GCP Basics

Languages Available:
- Chinese (Simplified)
- German
- Japanese

Partners: FDA

GCP/ICH Obligations of Sponsors, Monitors, and Investigators

This course addresses the GCP obligations of sponsors, monitors, and investigators as described in the ICH GCP Guideline.


Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- GCP Basics

Content Bundles:
- Good Clinical Practices (GCP)

Partners: FDA Corexcel

General Data Protection Regulation

This course covers the European Union’s (EU’s) General Data Protection Regulation (GDPR), which is a harmonized data privacy law across Europe. Topics in this course include: General Provisions and Principles, Rights of the Data Subject, Data Processors and Controllers, and Other Considerations. After completing this course, learners will be able to recognize the general provisions of the GDPR, and identify data subject rights under the Regulation. Learners will also be able to identify controller and processor obligations related to data privacy and security.

Format: eLearning (Editable) - CREATE, eLearning - EduFlex, eLearning - SCORM

Libraries:
- Not specified

Languages Available:
- French (European) (DP01)
- German (DP01)
- Spanish (Spain) (DP01)
General Overview and Philosophy of IEC 60601

Build a foundational understanding of how the IEC 60601-1 standard mitigates shock, mechanical, radiation, fire and other hazards and learn how the risk of each of the identified hazards is determined and reduced.

Format:
Libraries: Engineering Safety
Functional Areas: IEC 60601

General Valve Maintenance

General Valve Maintenance explains the function of valves in a pipeline system and the importance of visual inspections and maintenance to ensure that they work properly. It also discusses the qualities of a proper lubricant/sealant, how and when they should be used, and the equipment used to apply them. Common abnormal operating conditions (AOCs) that may be encountered while inspecting or maintaining valves are identified, including proper reactions.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Global Anti-Bribery

This course introduces global anti-bribery laws and provides basic principles and specific guidelines for complying with anti-bribery laws around the world.

Libraries: Ethics & Corporate Responsibility
Functional Areas: Anti-Corruption
Content Bundles: Corporate Compliance - Pharmaceutical, Corporate Compliance - Medical Device, Corporate Compliance - General Industry
Languages Available: Spanish (Latin America) (ETHICS14), German (ETHICS14), Italian (ETHICS14), French (European) (ETHICS14), Chinese (Simplified) (ETHICS14), Japanese (ETHICS14), Polish (ETHICS14), Portuguese (Brazil) (ETHICS14), Russian (ETHICS14), Spanish (Spain) (ETHICS14), Turkish (ETHICS14)

Global Anti-Bribery: UK

This training introduces global anti-bribery laws and provides basic principles and specific guidelines for complying with anti-bribery laws around the world.

Format: eLearning - Magazine
Libraries: Ethics & Corporate Responsibility
Functional Areas: Ethics Basics

Global Fair Competition Laws

Fair competition laws help to preserve a level competitive playing field for companies. This course covers the basic principles and laws governing fair competition. Topics in this course include: Definitions, Horizontal Agreements, Vertical Agreements, Other Key Considerations, Laws, EU Law — General Considerations, and EU Law — Specific Considerations. After completing this course, learners will be able to recognize the principles and laws that ensure fair competition globally.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Ethics & Corporate Responsibility
Functional Areas: Corporate Compliance Basics, Ethics Basics
Languages Available: German, French (European), Chinese (Simplified), Spanish (Spain), Japanese
Global Regulatory Strategy and Planning Process

This course discusses creating the strategy and planning documents that help companies align the development of new products with the regulatory submission process for those products. Along with the regulatory plan, a company's regulatory strategy describes the overall regulatory approach and the specific tactical steps required to meet regulatory objectives for the product. Topics in this course include: Purpose, Strategy Elements, and Plan Elements. After completing this course, learners will be able to identify the elements of a regulatory strategy and plan that can meet your company's development needs while meeting regulatory submission requirements for a variety of regulatory environments.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:
- Medical Device GMPs
- Global Regulatory

Functional Areas:
- Medical Device Market Entry

Languages Available:
- Chinese (Simplified) (DEV54_SCH)
- Japanese (DEV54_JP)
- Korean (DEV54_KOR)

Glutaraldehyde

Glutaraldehyde is a chemical used widely as a preservative, disinfectant, and sterilizing agent. Exposure to as little as 0.1 PPM (parts per million) in air can cause eye and respiratory irritation, and dermatitis. This course presents information about the hazards of glutaraldehyde, as well as information resources, and methods to protect against the effects of glutaraldehyde.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Environmental Health and Safety
- EHS Basics

GMP Principles for Batch Records

This course explains the Good Manufacturing Practices associated with batch records. Topics in this course include: Record Requirements, Manufacturing Records, Packaging Records, Deviations, and Batch Record Review. After completing this course, learners will be able to identify the regulatory requirements for batch records and recognize how to properly create and maintain batch records.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Partners: FDA

Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- Pharmaceutical GMPs - Batch Records

Languages Available:
- Spanish (Latin America) (PHA60)
- German (PHA60)
- French (European) (PHA60)
- Dutch (PHA60)
- Chinese (Simplified) (PHA60)
- Japanese (PHA60)

GMP Principles of SOPs

Working within SOPs is critical to making high-quality products that comply with FDA regulations. This course describes the basic GMP principles involved in creating SOPs. Topics include the contents of an SOP, the proper procedure for changing an SOP, and appropriate use of an SOP. After completing this course, you will be able to identify what SOPs are, what their purpose is, and how they are structured. You will be able to recognize how to handle changes to SOPs, as well as how SOPs are used in the workplace.


Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- Pharmaceutical GMP Basics

Languages Available:
- Spanish (Latin America) (PHA64)
- German (PHA64)
- French (European) (PHA64)
- Chinese (Simplified) (PHA64)
- Japanese (PHA64)
- Korean (PHA64)
GMP Updates: Supply Chain Quality and Emerging Compliance Concerns

Supply chain activities provide the natural resources and raw materials that manufacturers transform into a finished product. This course describes why supply chain quality has evolved as a critical concern in the medical device and pharmaceutical industries and what manufacturers can do to better manage supply chain quality. Topics in this course include: Challenges, Responses, and Company Improvements. After completing this course, learners will be able to recognize how regulators are responding to supplier quality concerns and identify what manufacturers can do to better manage supply chain quality.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Medical Device GMPs
- Pharmaceutical GMPs

Languages Available:  
- Chinese (Simplified)
- Japanese
- German

Good Clinical Practices (GCPs) for New Product Investigations

This course describes the general requirements of Good Clinical Practice (GCP) for new product investigations for the protection of human subjects, as well as information regarding the concepts, individuals, and groups involved with them. Topics in this course include: Clinical Trial Process, Clinical Trial Team, Specific GCP Requirements, and Documentation Requirements. After completing this course, learners will be able to recognize the basic concepts and key elements of GCP, including documentation, purpose, subject protection, and regulatory authority requirements.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:  
- Clinical: Medical Device
- Clinical: Pharmaceutical

Languages Available:  
- Chinese (Simplified)
- German
- Japanese

Good Documentation Practices for Medical Device Manufacturers

This course presents the critical importance of creating and maintaining good documents for medical device manufacturers. Learners will identify the stages of the Documentation Life Cycle, recognize important types of documents, recognize how documentation is controlled, identify the important requirements of electronic recordkeeping, and recognize best practices for recording and correcting data.


Libraries:  
- Medical Device GMPs
- Global Regulatory

Languages Available:  
- Spanish (Latin America) (DEV56)
- German (DEV56)
- French (European) (DEV56)
- Chinese (Simplified) (DEV56)
- Japanese (DEV56)

Good Laboratory Practices (GLPs)

Nonclinical laboratory studies are one of the first steps taken in bringing a new drug, device, or biologic to the marketplace, so it is important that practices are in place to ensure the reliability of the study and the safety and efficacy of the product. This course gives the learner an introduction to Good Laboratory Practice (GLP) Regulations and their application to nonclinical animal safety and toxicology studies. Topics in this course include: GLP Guidance, Personnel, Protocol, Documentation, and Inspections. After completing this course, learners will be able to recognize the general characteristics of GLPs and identify how they apply to nonclinical studies.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:  
- Clinical: Pharmaceutical

Languages Available:  
- Chinese (Simplified)
- Japanese
- German
Gowning for Sterile Manufacturing

Because of the importance of preventing contamination in finished sterilized pharmaceuticals or medical devices, anyone involved in the production of these products must have a basic knowledge of sanitation and sterilization, the microbiological principles involved, and the importance of proper gowns and working in cleanrooms. This course covers requirements of the European Union (EU) and FDA. Topics in this course include Regulations, Contaminants, and Gowning Procedures. After completing this course, you will be able to identify the sources and types of contamination in a manufacturing environment, recognize the importance of health issues and personal hygiene, and identify the staged entry and use of cleanrooms. You will also be able to recognize important practices and procedures for proper gowns. Before taking this course, make sure you have completed Principles of Aseptic Processing and Principles of Sterilization.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Medical Device GMPs
- Pharmaceutical GMPs
- Global Regulatory

**Functional Areas:**
- Maintenance and Facilities

**Content Bundles:**
- Maintenance and Facilities - Basics
- Basics of Aseptic Processing

Guidelines for Proctoring Tests and Evaluations

Guidelines for Proctoring Tests and Evaluations discusses the importance of and offers recommended guidelines for quality control during operator qualification examinations. This course also states the responsibilities of the mentor, proctor, and evaluator, as well as ways to validate testing using ExxTend Learning™.

**Format:**

**Libraries:**
- DOT Operator Qualification - Oil And Gas Pipeline

**Functional Areas:**
- Midstream Topics

Guidelines of Workplace Safety

This course explains how both employees and employers uphold safety in the workplace. Topics in this course include: Causes of Accidents, Accidents and Prevention, Hazards in the Workplace, Employer Role, and Your Role. After completing this course, learners will be able to recognize potential workplace accidents and hazards that may be prevented in order to maintain workplace safety.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Environmental Health and Safety
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

**Functional Areas:**
- Workplace Safety

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Languages Available:
- German
- French (European)
- Spanish (Spain)
- Chinese (Simplified)
- Japanese

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GxPs

Regulated Good Practices (GxPs) apply to the development, clinical testing and manufacture of drugs, biological products and medical devices to ensure their safety, efficacy, and security. This course discusses the manner in which regulatory authorities oversee the drug, biologic, and device development and manufacturing processes using GxP regulations. Topics in this course include: GLPs, GCPs, and GMPs. After completing this course, you will be able to identify what practices comprise the GxP regulations. You will also recognize how these practices relate to each step in the development and manufacture of new drugs, biologics, and medical devices.


Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical
- Pharmaceutical GMPs

Languages Available:
- French (European) (PHDV61)
- Chinese (Simplified) (PHDV61)
- Japanese (PHDV61)

Functional Areas:
- GxP Basics

Partners: FDA

Handling a Product Recall

This course defines product recalls and explains their impact on the manufacturer, FDA's requirements and enforcement when dealing with a product recall, and the basic steps for handling a recall. Topics include: Procedures, Roles, Effects, and Communication. After completing this course, learners will be able to recognize the definition of “product recall”, the impact of a product recall on a manufacturer, and FDA's requirements and enforcement authorities when dealing with a product recall. Learners will also be able to identify the basic steps for handling a recall.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Languages Available:
- Chinese (Simplified) (PHDV64_SCH)
- Japanese (PHDV64_JP)
- Korean (PHDV64_KOR)

Functional Areas:
- GMPs - Recalls

Partners: FDA

Handling an FDA Inspection

This course addresses the roles and responsibilities of personnel during an FDA inspection. Topics in this course include Personnel Conduct, Inspection Types, Process, Records, Photos and Samples, Concluding an Inspection, and Enforcement. After completing this course, learners will be able to identify the basics of handling an FDA Good Manufacturing Practice (GMP) inspection.


Libraries:
- FDA Inspections and Enforcement
- Medical Device GMPs
- Pharmaceutical GMPs

Languages Available:
- German (PHDV74)
- French (European) (PHDV74)
- Chinese (Simplified) (PHDV74)
- Japanese (PHDV74)
- Korean (PHDV74)
- Spanish (Spain) (PHDV74)

Functional Areas:
- GMP Inspection Readiness
- FDA Inspection Readiness

Content Bundles:
- GMP Inspection Readiness

Partners: FDA

Handling Confidential Information

This course explores the importance of protecting confidential information in order to preserve privacy and maintain a competitive edge. After completing this course you will be able to recognize the definition of confidential information, identify ways that information is made vulnerable in the workplace, and recognize specific policies, laws, and examples that relate to confidentiality.


Libraries:
- Ethics & Corporate Responsibility

Languages Available:
- Italian (ETHICS10)
- French (European) (ETHICS10)
- Chinese (Simplified) (ETHICS10)
- Japanese (ETHICS10)
- Spanish (Spain) (ETHICS10)

Functional Areas:
- Corporate Ethics

Content Bundles:
- Corporate Compliance - Plan Sponsors
Supervisors and managers must take all complaints and incidents of sexual harassment seriously and should respond quickly and appropriately. This course describes the different types of sexual harassment that can occur in the workplace and how to prevent, monitor, and report these events if they occur. Topics in this course include: Laws and Policies, Types of Sexual Harassment, Prevention and Monitoring, Enforcement, Reporting Harassment, Investigating Harassment, and Retaliation. After completing this course, learners will be able to recognize what actions constitute harassment in the workplace.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: • Ethics & Corporate Responsibility
• HR Compliance & Risk Management

Analyze the best practices for addressing and preventing harassment in the workplace. Topics in this course include: Definition, Sexual Harassment, Laws, Prevention, and Reporting. After completing this course, learners will be able to identify harassing behavior, avoid harassing behavior, and properly address harassing behavior in the workplace.


Libraries: • HR Compliance & Risk Management
• Ethics & Corporate Responsibility

Hazard Communication protects employees by providing information about hazardous chemicals and how to handle them correctly. This course identifies hazardous materials and ways to minimize risk when handling these substances. Topics in this course include: Hazard Identification, Routes of Exposure, Labeling, Safety Data Sheet (SDS), Minimizing Risks, and Best Practices. After completing this course, learners will be able to recognize hazardous materials and their classifications in the Hazard Communication Standard.

Languages Available: Spanish (Latin America), German

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: • Environmental Health and Safety

When you are working with a hazardous chemical, you need to know what it is, what it does and how to stay safe around it. Standards organizations around the world are harmonizing Safety Data Sheets (SDSs) to ensure that each sheet is consistent and thorough in explaining the necessary information to keep you safe around hazardous substances. This course explains SDSs to managers and front line workers in industries and environments that require the use of hazardous substances.

Libraries: • DOT Operator Qualification - Oil And Gas Pipeline
Hazardous Waste Determination

The US Environmental Protection Agency (EPA) regulates hazardous wastes through the Resource Conservation and Recovery Act (RCRA). In this course, participants will learn how solid waste is defined, what is contained in a solid waste inventory, and how hazardous waste determinations are made. Topics in this course include: Solid Waste, Hazardous Waste, and Regulations. After completing this course, learners will be able to recognize what the definition of solid waste is, recognize what is contained in a solid waste inventory, and identify how hazardous waste determinations are made.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Environmental Health and Safety
- Hazardous Materials

Hazardous Waste Disposal

Industries operating in the US must track all hazardous wastes from generation to disposal and beyond. The US Environmental Protection Agency (EPA) has created forms that help companies that generate, transport, store, and dispose of hazardous wastes track them throughout their lifecycle. This course presents the procedure for tracking the disposal of hazardous waste from a hazardous waste generator to a TSDF. Topics include: Definitions, UHWM, Land Disposal Restriction Form, and Biennial Report. After completing this course, learners will be able to recognize the correct procedures for shipping of hazardous waste that requires disposal.

Format: eLearning - SCORM, eLearning - EduFlex
Libraries:
- Environmental Health and Safety
- Hazardous Materials

Hazardous Waste Drum Management

Drum containers are commonly used in industry for storage, transportation, and disposal of hazardous waste. This course presents basic information on hazardous waste drum management. Topics in this course include: Labels, Handling Drums, Storing Drums, and Empty Containers. After completing this course, learners will be able to properly identify hazardous waste drums and recognize whether related appropriate safety guidelines and regulations are being applied.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Environmental Health and Safety
- Hazardous Materials

HAZWOPER Awareness

The exposure to hazardous chemicals is a risk faced by Americans in workplaces every day. This course identifies hazardous substances that can be found in the workplace and cause harm to employees if not properly handled. Topics in this course include: Hazards, Spills and Releases, Emergency Response Plan, HAZMAT Team, DOT Labeling, OSHA Labels, Waste Labels, and Emergency Response Guidebook (ERG). After completing this course, learners will be able to recognize how to properly respond to a spill or release of a hazardous chemical.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries:
- Environmental Health and Safety
- Hazardous Materials
Content Bundles:
- EHS for Life Science Companies - Basics

Languages Available:
- Spanish (Latin America) (EHS42)
HAZWOPER Refresher Training - Module 7 - Respiratory Protection (US)

This is Part Seven of a 13-part series of modules on HAZWOPER designed to provide the annual refresher training as required by OSHA for all employees affected by this regulation. Part Seven covers respiratory protection. Respirators provide vital protection against chemicals and oxygen-deficient atmospheres. For this reason it is critical to know how to select and use the appropriate respirator for the job. All respirators are not created equal: not all of them will provide protection in atmospheres with low oxygen or certain other atmospheric hazards. In this module, those with a role in hazardous waste operations and emergency response will learn how to protect themselves from the breathing hazards they may face.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

HAZWOPER Refresher Training - Module 8 - Personal Protective Equipment (PPE) (US)

This is Part Eight of a 13-part series of modules on HAZWOPER designed to provide the annual refresher training as required by OSHA for all employees affected by this regulation. Part Eight covers PPE, personal protective equipment, your last line of defense against hazardous materials in your work environment. Although PPE cannot provide protection from all exposure, when properly selected and worn it can prevent unnecessary harmful exposures. For this reason it is critical to select the appropriate protective equipment for the job.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Hearing Conservation

The ability to hear is important in everyday life, particularly for safety in the workplace. In this course, the participant will learn how to reduce the risk of sound-induced hearing loss. Participants will also learn how hearing loss occurs, how hearing can be monitored, and methods for protecting their hearing.

Format: eLearning - HIP2

Libraries:
- Environmental Health and Safety

Functional Areas:
- Professional Development

Heat Stress

Exposure to extreme heat can result in occupational illnesses and injuries. This course explains what heat stress is, who is at risk of heat stress, the effects of heat stress on an individual, and the measures workers can take to reduce the likelihood of injuring themselves due to heat stress. Topics in this course include: Natural Cooling Methods, Effects of Heat Stress, Heat Stress Dynamics, Engineering Controls, and Work Practice Controls. After completing this course, learners will be able to recognize the definition of heat stress, the hazards associated with it, and ways to treat and prevent it.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:
- Environmental Health and Safety

Functional Areas:
- Workplace Safety

Languages Available:
- Spanish (Latin America)
High Purity Water Systems

Because water quality can directly impact product quality, GMP regulations require that water receive the same scrutiny, monitoring, and control as any other critical raw material used in manufacturing processes. This course describes the typical uses of water in pharmaceutical and medical device manufacturing. Topics in this course include: Types of Water, Quality Determination, WFI System, Monitoring Process, Monitoring Approaches, System Problems, and Solutions. After completing this course, learners will be able to recognize water types used in manufacturing, monitoring processes, and solutions to problems within high purity water systems.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- GMP Basic Concepts

Partners: FDA

HIPAA -- The Impact On Clinical Research

Congress enacted the Health Insurance Portability and Accountability Act (HIPAA) to protect patient privacy and confidentiality. This course explains the history of HIPAA implementation, legal entities involved in HIPAA oversight and compliance, and the impact HIPAA has on clinical research in the United States. Topics in this course include: Privacy Requirements, PHI Waivers, Current Regulations, Limited Data Sets, Exceptions and Enforcement, and Future Clinical Research. After completing this course, learners will be able to identify penalties for violations of HIPAA Privacy requirements.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- GCP Basics

Languages Available:
- French (European) (GCP05)
- Spanish (Spain) (GCP05)
- Chinese (Simplified) (GCP05)
- German (GCP05)
- Japanese (GCP05)

HIPAA and Privacy Guidelines for Medical Device Sales Representatives

It is important for Medical Device Sales representatives to know how our sensitivity to customers' privacy concerns is critical to maintaining their trust. This course outlines the HIPAA Privacy Rule and how it affects daily activities. Topics in this course include: Effects of HIPAA, Products and Software, Assistance and Training, and Patient Issues. After completing this course, learners will be able to recognize the basic provisions of the HIPAA Privacy Rule and how HIPAA affects detailing and customer support activities.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:
- Medical Device - Sales & Marketing
- Clinical: Pharmaceutical

Functional Areas:
- Vendor Credentialing
- Pharmaceutical Sales Compliance

Content Bundles:
- Vendor Credentialing

HIPAA and Privacy Guidelines for Pharmaceutical Sales Representatives

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Libraries:
- Pharmaceutical - Sales & Marketing

Functional Areas:
- Pharmaceutical Sales Compliance
HIPAA Privacy: Role-Based Training I (Incidental PHI Contact)

This course is designed for employees who do not access PHI as part of their regular duties, but need to know what they should do when they do come into contact with PHI. Topics in this course include: PHI Encounters and Compliance. After completing this course, learners will be able to recognize how to apply HIPAA's privacy requirements to situations they encounter every day.

Format: eLearning (Editable) - CREATE, eLearning - SCORM, eLearning - EduFlex

Libraries: HIPAA

Functional Areas: Healthcare: HIPAA

HIPAA Privacy: Role-Based Training II (Internal Uses of PHI)

This course is designed for employees who are authorized to use protected health information (PHI) as part of their regular duties. Topics in this course include: Handling PHI and Compliance. After completing this course, learners will be able to recognize how to apply HIPAA's privacy requirements to situations they encounter every day.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: HIPAA

Functional Areas: Healthcare: HIPAA

HIPAA Privacy: Role-Based Training III (Uses and Disclosures of PHI)

This course is designed for employees who are authorized to use, disclose, and request PHI as part of their regular duties. After completing this course, learners will be able to apply HIPAA's privacy requirements to situations they encounter every day. Before taking this course, learners must complete one or more of the following: Business Practices for Protecting PHI, HIPAA: General Awareness, HIPAA: Privacy Standards.


Libraries: HIPAA

Functional Areas: HIPAA

HIPAA Privacy: Role-Based Training IV (Managers, Supervisors, and Compliance Staff)

This course is designed for HIPAA privacy officials, supporting HIPAA compliance staff, and managers, including those who have additional compliance responsibilities, such as ownership of PHI sources or information application and system purchases. After completing this course, learners will be able to apply HIPAA's privacy requirements to situations they encounter every day. Before taking this course, learners must complete one or more of the following: Business Practices for Protecting PHI, HIPAA: General Awareness, HIPAA: Privacy Standards. Learners must also complete HIPAA Privacy: Role-Based Training III (Uses and Disclosures of PHI).

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: HIPAA

Functional Areas: Healthcare: HIPAA
HIPAA: General Awareness

This course is designed to provide all employees and associates with an in-depth overview of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy, security, and data standardization requirements from a health plan perspective. This course describes the updated requirements that were included in the Health Information Technology for Economic and Clinical Health Act (HITECH), which was signed into law February 2009. Topics in this course include: Privacy Standards, Security Standards, Data Standardization, and Enforcement. After completing this course, learners will be able to identify HIPAA regulations and ways to keep members' PHI secure.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:
- HIPAA
- Medical Device - Sales & Marketing
- Pharmaceutical - Sales & Marketing
- Ethics & Corporate Responsibility

Functional Areas:
- Healthcare: HIPAA

HIPAA: Privacy Standards

Health plan members must be able to trust that shared information will be protected and remain confidential. This course provides an in-depth look at the Privacy Standards included in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the requirements of the Health Information Technology for Economic and Clinical Health Act (HITECH). Topics in this course include: Permitted Uses and Disclosures, Authorized Uses and Disclosures, Minimum Necessary, Individual Rights, and Breach Disclosures. After completing this course, learners will be able to recognize the rules governing the use and disclosure of a member's protected health information.


Libraries:
- HIPAA

Functional Areas:
- Healthcare: HIPAA

Hiring and Firing

Hiring is an important factor in creating a solid workforce, and firing is a tool to ensure productivity. This course provides techniques for making good hiring decisions, terminating employees in a consistent and fair manner, and avoiding lawsuits resulting from the hiring and firing process. Topics in this course include: Regulations, Hiring, Interviewing, Testing, and Firing. After completing this course, learners should recognize several tools that will assist in the hiring and firing processes. Learners will also identify how to handle difficult employee situations.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:
- HR Compliance
Hoists and Rigging

This course covers the use of hoists and rigging equipment to move materials safely in the workplace. Topics in this course include: Hoists; Rigging; Hitches; Evaluate and Select; Inspect; and Verification, Lifting, and Moving. After completing this course, learners will be able to recognize the purpose of hoists, rigging, slings, connective hardware, and hitches. Learners will be able to identify the steps in safe use of hoists and rigging. Learners will also be able to recognize the detailed procedures involved with each step.

Format: eLearning - HIP2

Libraries:
- Environmental Health and Safety
- Workplace Safety

Hot Tapping

Hot Tapping addresses the mechanical procedures, safety precautions, and limitations of pressurized pipeline tapping; procedures and precautions for preparing a pipeline for a hot tap operation; and mechanical procedures and precautions for pressurized pipeline stopping.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline
- Midstream Topics

Hot Work Permits

Hot work must be performed in a way that ensures the safety of all employees performing hot work in non-protected areas, where protection from high heat sources is limited. This course covers the appropriate practices for hot work permits. Topics in this course include: Special Considerations and Responsibilities. After completing this course, learners will be able to identify the process of hot work area evaluation and recognize appropriate practices while performing hot work.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Environmental Health and Safety
- EHS Basics

Languages Available:
Spanish (Latin America)

How to Build a UL CREATE Course

In this course, you will learn how to build an e-learning course using UL CREATE. This course will walk you through adding pages, content and interactions. We will also cover applying themes, previewing your course, and publishing to your audience. Topics in this course include: Adding a New Course, Inspecting the Build Course Mode, Building the Course, Page Setup, Adding Page Content, Adding a Quiz, Selecting a Theme, Previewing Your Course, and Publishing. After completing this course, learners will be able to identify how to build their own training courses with UL CREATE.

Format: eLearning (Editable) - CREATE

Libraries:
- Not specified
How to Edit a UL CREATE Course

In this course, you will learn how to make changes to UL CREATE courses. This course will cover the different aspects of editing a course including modifying content and interactions. Topics in this course include: Editing Page Sections, Editing Content, Editing Entire Pages, and Publishing. After completing this course, learners will be able to identify how to edit an existing UL CREATE course.

Format: eLearning (Editable) - CREATE

Libraries:

- Not specified

How to Meet Drug Retention and Stability Testing Requirements

This course is designed to provide the learner with an understanding of the principles of drug stability testing and requirements for maintaining reserve samples. The goal of this lesson is for the learner to gain an understanding of shelf life and product expiration dating, and respect for the expiration and product storage labeling information, based on its effect on product safety and effectiveness.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMP Basics

Partners: FDA

HP: Compliance Program General Session

The Office of Inspector General (OIG) guidance promotes Compliance Programs for all healthcare organizations. This course is designed to fulfill the OIG and Centers for Medicare and Medicaid Services (CMS) requirement for a general training session on effective Compliance Programs. Topics in this course include: Definitions, Core Elements, Standards and Leadership, Training, Communication, Disciplinary Standards, and Monitoring and Responding to Compliance Issues. After completing this course, learners will be able to recognize the elements of an effective Compliance Program, FWA laws, and the resources available for compliance with government regulations.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:

- Healthcare: General

Functional Areas:

- Healthcare: Compliance Topics

Human Performance Systems

Human Performance Systems addresses trends and economic forces driving change in the pipeline industry; competence, performance, and productivity; the human performance model; the human performance system; and human performance improvement.

Format:

Libraries:

- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:

- Midstream Topics
Hydrogen Sulfide (H2S)

Hydrogen sulfide poses a wide range of hazards to exposed workers, from mild health effects to death. This course describes the hazards of hydrogen sulfide, detection, and exposure reduction methods. Topics in this course include: Hazards, Limits, Assessing Exposure, Controls, and First Aid. After completing this course, learners will be able to recognize appropriate responses in an emergency involving hydrogen sulfide.

Format: eLearning - SCORM, eLearning - EduFlex

EHS48

Languages Available: Spanish (Latin America)

ICH GCP Obligations of Investigators Conducting Clinical Trials

This course addresses the obligations of investigators as described by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). It focuses on the investigator's responsibilities to protect the rights and welfare of human subjects and ensure data integrity. By extension, these responsibilities also apply to other investigation site staff involved in the planning, conduct, recording, and reporting of clinical trials.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Partners: Corexcel

GCP02

ICH Q7: Resources and Materials Management

This is the second in a series of courses designed to instruct on Good Manufacturing Practices (GMPs) for Active Pharmaceutical Ingredients (APIs), as set out by the ICH Q7 Guideline. This course covers qualifications for personnel, requirements for buildings used in API manufacturing, considerations for API manufacturing equipment, and materials management. Learners should have a working knowledge of current GMPs for drug products as set out in CFR 21 Parts 210 and 211. Learners should also have a basic understanding of chemical and biological processes used in the manufacture of Active Pharmaceutical Ingredients. Learners should have completed the course ICH Q7: Introduction and Quality Management.

Format: eLearning - EduFlex, eLearning - SCORM

ICHreg02

ICH Q7A: Introduction and Quality Management

This is the first in a series of courses designed to instruct on current good manufacturing practices (GMPs) for active pharmaceutical ingredients (APIs), as set out by the ICH Q7 Guideline. This course covers the Introduction to ICH Q7 and Quality Management for API manufacture. The learner should have a working knowledge of current GMPs for drug products as set out in the Code of Federal Regulations, CFR 21 Parts 210 and 211, as well as a basic understanding of chemical and biological processes used in the manufacture of Active Pharmaceutical Ingredients.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

ICHreg01
IEC 61010 — Measurement, Control, and Laboratory Use Equipment

Because measurement, control, and laboratory equipment is crucial to the quality and consistency of medical products, IEC 61010 exists to ensure those types of equipment meet certain standards and create safe, consistent products. This course covers the IEC 61010 standard for measurement, control, and laboratory use equipment. Topics in this course include: Structure, Testing Conditions, Markings and Documentation, Insulation Factors, Hazard Testing, and Risk Assessment. After completing this course, you will recognize the basic standards that are utilized in evaluating measurement, control, and laboratory equipment.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Engineering Safety
Functional Areas: IEC 61010

IEC 61010-1: Measurement, Control, and Laboratory Use Equipment — Standards and Application

Because measurement, control, and laboratory equipment is crucial to the quality and consistency of medical devices, IEC 61010-1 exists to ensure those types of equipment meet certain standards and create safe, consistent products. This course covers the IEC 61010-1 standard for measurement, control, and laboratory use equipment as well as application methods. Topics in this course include: Insulation Factors, Hazard Testing, and Risk Assessment. After completing this course, learners will be able to recognize standards and application methods that are utilized in evaluating measurement, control, and laboratory equipment.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Engineering Safety
Functional Areas: IEC 61010

IEC 62304: Medical Device Software Development Process and Risk Management

This course describes IEC 62304’s requirements for any software development process involving medical devices. Topics in this course include: Software Development Process; Software Maintenance; Software Risk Management; Software Configuration Management; and Problem Revolution. After completing this course, learners will be able to recognize IEC 62304’s software development requirements throughout the software’s life cycle.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Engineering Safety
Functional Areas: Medical Device, Risk Management

IEC 62304: Medical Device Software Life Cycle Processes and Requirements

This course introduces IEC 62304, the standard that contains the requirements for the medical device software life cycle process, and explains the key processes for the software life cycle. Topics in this course include: General Requirements, Safety Classifications, Legacy Software, and Implementation. After completing this course, learners will be able to recognize the purpose of the IEC 62304 standard, recognize its basic requirements, identify safety classifications under the standard, recognize implications of legacy software, and identify implementation considerations.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Engineering Safety
Functional Areas: Risk Management, Medical Device

Languages Available:
- Chinese (Simplified)
- Japanese
- Korean

Languages Available:
- Chinese (Simplified)
- French (European)
- German
- Japanese
- Spanish (Spain)

Languages Available:
- Japanese
Implementing an Equipment Qualification Program

A well-developed and established equipment qualification program allows a company to meet current GMP requirements and save operational costs at the same time. This course provides an overview of the equipment qualification requirements, for the US and European Union, that apply to the pharmaceutical, biotechnology, and medical device industries. Topics in this course include: Protocol, Design, Installation, Operation, Performance, and Legacy Equipment. After completing this course, learners will be able to identify the steps in successful implementation of an equipment qualification program.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: 
- Medical Device GMPs
- Pharmaceutical GMPs
Functional Areas: 
- GMP Basic Concepts

Languages Available: 
Chinese (Simplified)
Japanese

Import Operations 1: Background

The first in a series of three courses, this course introduces FDA's import program and the laws applied to products offered for entry into the US and products intended for export from the US. Topics in this course include: Enforcement Approaches, Importers vs. Domestic, FD&C Act, 21 CFR, 19 CFR, 18 USC, and Resources. After completing this course, learners will be able to recognize how FDA ensures that imported products meet US public health standards. Learners will also be able to identify the differences between the regulation of domestic and imported products, the regulations that apply to imported products, and how the FD&C Act, the Code of Federal Regulations, and the United States Code address imports.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: 
- FDA Inspections and Enforcement
Functional Areas: 
- FDA Import Operations

Languages Available: 
Chinese (Simplified) (FDA37_SCH)
Japanese (FDA37_JP)
Korean (FDA37_KOR)

Import Operations 2: The Process

The second in a series of three, this course addresses FDA import and export programs, procedures, and policies and introduces the process followed during import proceedings. This course concentrates on how FDA regulates products pre-entry, types of entries, how FDA makes decisions about entries, and the resources available to assist with entry decisions. Topics in this course include: Pre-Entry, Food Safety, Entries, Entry Decisions, Resources, Examination, Analysis, Admissibility, and Enforcement. After completing this course, learners will be able to recognize the approaches and processes FDA uses to determine whether or not an import entry is in compliance with current import regulations.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: 
- FDA Inspections and Enforcement
Functional Areas: 
- FDA Import Operations

Languages Available: 
Chinese (Simplified) (FDA42_SCH)
Japanese (FDA42_JP)
Korean (FDA42_KOR)

Import Operations 3: Other Activities

This course continues discussion on import operations. Topics in this course include: Filers, Sharing Information, Exports, Export Certificates, and Shared Responsibility. After completing this course, learners will be able to recognize how import filers participate in OASIS; how FDA identifies and removes violative imports from the US market; how FDA regulates exports; and what other agencies share responsibilities for imports with FDA. Learners will also be able to recognize the different types of export certificates and their significance.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: 
- FDA Inspections and Enforcement
Functional Areas: 
- FDA Import Operations

Languages Available: 
Chinese (Simplified) (FDA43_SCH)
Japanese (FDA43_JP)
Korean (FDA43_KOR)
Improving Productivity

Mastering productivity skills will make employees more valuable, and their work more satisfying. This course identifies basic skills for setting goals, prioritizing tasks, and managing time. This course also illustrates how to avoid time-wasters, delegate appropriately, and make efficient decisions. Topics in this course include: Productivity, Values, Becoming a Goal Getter, Planning, Time Wasters, Delegating, Individual Decisions, Group Decisions, Networking, and Teamwork. After completing this course, learners will be able to recognize the basic skills for setting goals, prioritizing tasks, and managing time.

Format: eLearning - EduFlex, eLearning - SCORM

Languages Available: Spanish (Spain)

Incident Command System and Natural Gas Emergencies

Incident Command System and Natural Gas Emergencies addresses the Incident Command System (ICS) and Natural Gas Emergencies training program, Incident Commander responsibilities and staff, kinds of pipeline emergencies and company response, implementing a successful ICS, the role of NIMS in incident management, and maintaining relations with emergency response officials.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Infection Prevention and Control

In the United States, there are an estimated 8.8 million persons who work in healthcare professions. Healthcare workers may acquire infections from patients or other personnel, household members, or other community contacts, and transmit infections to them as well. Studies indicate that well-organized infection control programs can prevent one-third of infections acquired at healthcare facilities, yet only 6-9% are actually prevented because specific safe work practices are not followed. This course presents information about how infections are transmitted and methods for infection control.

Format: eLearning - HIP2

Libraries: Environmental Health and Safety

Functional Areas: EHS Basics for Healthcare Workers

Information Security

Information security is critical for any business, and it is the law for healthcare organizations. This course addresses training on the HIPAA Security Standard for all management and staff and presents healthcare industry current practices as outlined by the HIPAA regulations. Topics in this course include Security Roles, Security Controls, Administrative Safeguards, Physical Safeguards, and Technical Safeguards. After completing this course, learners will be able to recognize the security policies, procedures, and controls that are part of our daily business routine. Learners will also be able to identify suspected security breaches and how to respond to them.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: HIPAA

Functional Areas: Healthcare: HIPAA
Informed Consent

The informed consent document and process are designed to serve as an ethical framework for safeguarding the rights and well-being of research participants. This course explains informed consent regulations and guidelines, the informed consent process, and the roles and responsibilities of clinical research professionals. Topics in this course include: Foundational Documents, Consent Document, Types, Exceptions, Pediatric Research, Managing Consent, and Verifying. After completing this course, learners will be able to identify key historical events that led to the current informed consent regulations and guidelines and will also be able to recognize the informed consent process as well as its documentation requirements.


Libraries: Clinical: Medical Device, Clinical: Pharmaceutical

Functional Areas: GCP Basics

Content Bundles: Good Clinical Practices (GCP)

Inspecting and Testing Control Valves

Inspecting and Testing Control Valves explains the purpose of control valves in a pipeline system. The different parts that make up a control valve assembly and their functions are discussed. The process for inspecting a control valve is also explained. Common abnormal operating conditions (AOCs) that may be encountered while inspecting and testing control valves are identified, including preferred reactions.

Format: DOT Operator Qualification - Oil And Gas Pipeline

Libraries: Midstream Topics

Functional Areas: Midstream Topics

Inspecting and Testing Pressure Limiting Devices

Inspecting and Testing Pressure Limiting Devices explains how a relief valve operates, along with different design features and their purpose. It also discusses the procedure for testing relief valves. Common abnormal operating conditions are discussed.

Format: DOT Operator Qualification - Oil And Gas Pipeline

Libraries: Midstream Topics

Functional Areas: Midstream Topics

Inspecting and Testing Regulators

Inspecting and Testing Regulators explains how a regulator operates, along with different design features and their purpose. The differences between a pilot-operated and a spring-operated regulator and how they work are explained. The procedure for testing regulators is also discussed. Common abnormal operating conditions (AOCs) that may be encountered while inspecting or testing regulators are identified, including possible reactions.

Format: DOT Operator Qualification - Oil And Gas Pipeline

Libraries: Midstream Topics

Functional Areas: Midstream Topics
Install Meters and Regulators - Commercial

Install Meters and Regulators - Commercial addresses the basic parts of a commercial gas distribution system, installation of meters and regulators, protecting a commercial gas system from pressure damage, meter and regulator selection, installation of a meter set and adjusting a meter's set point, testing for gas system leaks, and service wrap-up procedures.

Format:

Libraries:
- DOT Operator Qualification - Oil and Gas Pipeline

Functional Areas:
- Midstream Topics

Install Meters and Regulators - Residential

Install Meters and Regulators - Residential examines the basic parts of a residential gas distribution system, installation of meters and regulators, protecting a residential gas system from pressure damage, meter and regulator selection, installation of a meter set and adjusting a meter's set point, testing for gas system leaks, and service wrap-up procedures.

Format:

Libraries:
- DOT Operator Qualification - Oil and Gas Pipeline

Functional Areas:
- Midstream Topics

Installation of Anodes

Installation of Anodes explains the anode theory, the different types of anodes, a general outline for installing anodes, and a procedure for exothermic welding. Abnormal operating conditions (AOCs) that may be encountered while installing anodes for pipeline corrosion control are included.

Format:

Libraries:
- DOT Operator Qualification - Oil and Gas Pipeline

Functional Areas:
- Midstream Topics

Installation of Plastic Mains and Services - Part 1

Installation of Plastic Mains and Services - Part 1 addresses precautions and practices for handling and storing plastic pipe, installation of plastic pipe for natural gas main and service lines, installation of transition fittings, installation of excess flow valves, abandonment and reinstatement of mains and services, and installation of tracer wire.

Format:

Libraries:
- DOT Operator Qualification - Oil and Gas Pipeline

Functional Areas:
- Midstream Topics
Installation of Plastic Mains and Services - Part 2

Installation of Plastic Mains and Services - Part 2 addresses direct burial of plastic pipe; tie-ins and tapping service punch tees; squeezing plastic pipe, including the squeeze-off procedure; inserting plastic pipe in an existing line; pressure testing mains and services; purging mains; and repairing PVC pipe.

Format:
Libraries:  
DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:  
Midstream Topics

Installation of Steel Mains and Services

Installation of Steel Mains and Services addresses proper handling, storage and inspection of steel pipe; typical right-of-way and easement requirements, including pipeline depth and clearance from other underground structures; pipe installation requirements for overhead and underground highway, railroad, stream, river, and levee crossings; pipeline installation, including joining pipe by welding or with fittings, lowering-in, pressure testing, and backfilling the excavation; and steel Distribution Service line installation, connection to curb valves, and connection to the main tapping.

Format:
Libraries:  
DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:  
Midstream Topics

Installation of Test Stations

Installation of Test Stations addresses exothermic welding procedures; test station function; test stations used for pipe-to-soil surveys; test station installation methods; cable bonding techniques; soldering methods; and materials, spacing, and location. Abnormal operating conditions (AOCs) that may be encountered while installing test stations are included.

Format:
Libraries:  
DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:  
Midstream Topics

Interactions with Healthcare Professionals - Field

This course covers the guidelines, rules, and regulations that govern interactions between field sales representatives and healthcare professionals.

Format:  
eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:  
Pharmaceutical - Sales & Marketing

Functional Areas:  
Pharmaceutical Sales Compliance
Interactions with Healthcare Professionals - In-House

Pharmaceutical company interactions with healthcare professionals are subject to extensive regulatory scrutiny and should be conducted in compliance with internal and external guidelines, policies, rules, and regulations. This course covers the guidelines, rules, and regulations that govern interactions with healthcare professionals as well as the appropriate manner in which to conduct such interactions. Topics in this course include: Regulations and Guidance, Speaker Programs, Drug Adherence Programs, Patient Assistance Programs and Support for Independent Third Party Charities, Investigator Initiated Research Studies, Gifts, Meals and Entertainment, Professional Services, and Education. After completing this course, learners will be able to identify the guidelines, policies, rules, and regulations that govern interactions with healthcare professionals. Learners will also be able to identify the appropriate manner in which to conduct these interactions.


Libraries: Pharmaceutical - Sales & Marketing

Functional Areas: Pharmaceutical Sales Compliance

Interference: AC and DC

Interference: AC and DC explains the concepts of interference or stray current and its common sources, such as cathodic protection systems, DC transit systems, AC electrical transmission lines, and others. Testing methods and corrective actions for interference currents are also discussed. Abnormal operating conditions (AOCs) that may be encountered while testing and taking corrective actions for interference currents are included.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Internal Corrosion

Internal Corrosion explains the requirements and acceptable methods for pipe inspections. The different causes of internal pipe corrosion, monitoring, and corrosion control methods are also described. Industry standards for acceptable gas quality are included. Common abnormal operating conditions (AOCs) that may be encountered while monitoring corrosion are identified, including possible responses.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Interviewing Techniques

Interviews are an important part of virtually every operation performed by FDA investigators and analysts. This course identifies effective interviewing techniques and traits of an effective interviewer. Topics in this course include: FDA Interviewers, Preparation, Interviewees, Interviewer Traits, Effective Questions, and Nonverbal Behavior. After completing this course, learners will be able to recognize the fundamentals of conducting an effective interview. Learners will be able to identify the traits of a successful interviewer and the importance of appropriate interpersonal skills. Learners will also be able to identify appropriate questioning techniques to use in an interview.


Partners: FDA

Libraries: FDA Inspections and Enforcement, Pharmaceutical GMPs

Functional Areas: FDA Inspection Readiness
## Introduction to CFDA and CFDA Registration

This course introduces the basic structure of the China Food and Drug Administration (CFDA) and the process for approving medical devices in China.

**Languages Available:**
- Chinese (Simplified) (PHDV97)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Global Regulatory
  - Medical Device Market Entry

## Introduction to Data Integrity

This course provides foundational knowledge of the concepts of data integrity and quality. Topics in this course include: Regulatory Requirements, International Standards, Ensuring Data Integrity, and Evaluation and Review. After completing this course, learners will be able to identify requirements that help maintain data integrity and quality.

**Languages Available:**
- Chinese (Simplified) (DATA01)
  - German (DATA01)
  - French (European) (DATA01)
  - Spanish (Spain) (DATA01)

**Format:** eLearning - SCORM, eLearning - EduFlex, eLearning (Editable) - CREATE

**Libraries:**
- Data Integrity
  - Quality Assurance
  - Content Bundles:
    - Data Integrity

## Introduction to GMPs

Current Good Manufacturing Practices (cGMPs) are specific requirements that ensure safe manufacturing of pharmaceutical products and medical devices. This course describes the importance, purpose, and enforcement of cGMPs by FDA. Topics in this course include: History, Procedures, Documentation, Pharmaceutical Quality System, Responsibilities, and FDA Inspections. After completing this course, learners will be able to recognize basic cGMP requirements and identify the roles and responsibilities of pharmaceutical and medical device manufacturing employees.

**Languages Available:**
- German (PHA38)
  - Japanese (PHA38)
  - Chinese (Simplified) (PHA38)
  - French (European) (PHA38)
  - Portuguese (Brazil) (PHA38)
  - Spanish (Spain) (PHA38)
  - Hebrew (PHA38)

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Libraries:**
- Medical Device GMPs
  - Pharmaceutical GMPs
  - Content Bundles:
    - Pharmaceutical - GMP

## Introduction to Medicaid

This course discusses the many challenges state governors and legislators face in managing their Medicaid programs and provides a foundation of knowledge for health plans to make required changes to business and information system processes as a result of the Patient Protection and Affordable Care Act (ACA). With the passing of this landmark reform, the management of Medicaid programs has changed and is continuing to evolve with expanded Medicaid coverage and eligibility.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Languages Available:**
- German (PPACA03)
  - Japanese (PPACA03)
  - Chinese (Simplified) (PPACA03)
  - French (European) (PPACA03)
  - Portuguese (Brazil) (PPACA03)
  - Spanish (Spain) (PPACA03)

**Libraries:**
- PPACA
  - Healthcare: Affordable Care Act
**Introduction to Medical Device Health Care Compliance**

This course provides an introduction regarding the compliance of pertinent laws, regulations, and guidance that regulate the medical device industry. Topics in this course include: FDA Regulations, OIG, AdvaMed Code of Ethics, FCPA and False Claims Act, State Legislation and Sunshine Act Provisions. After completing this course, learners will be able to recognize the various laws, regulations, and guidance that regulate the medical device industry.

**Format**: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries**: Medical Device - Sales & Marketing

**Functional Areas**: Vendor Credentialing

**Content Bundles**: Vendor Credentialing

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**Introduction to Pharmaceutical Compliance**

This course introduces the agencies that govern standards of behavior in the pharmaceutical industry as well as the key requirements for compliant behavior.

**Format**: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries**: Pharmaceutical - Sales & Marketing

**Functional Areas**: Corporate Ethics, Sales Compliance

**Content Bundles**: Corporate Compliance - Pharmaceutical

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**Introduction to Risk Management**

Understand the role ISO 14971 plays within the IEC 60601 standards to demonstrate compliance with risk management requirements worldwide, including its use in the CB Scheme Test Report Form in order to document compliance.

**Format**: 

**Libraries**: Engineering Safety

**Functional Areas**: IEC 60601

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**Introduction to Specialty Pharmacy Management**

Specialty drugs are the fastest growing component of prescription drug expenditures because of enormous increases in availability and use, coupled with drug cost inflation. This course covers the proactive management of specialty medications in order to help payers control costs and maximize the value of these therapies. Topics in the course include: Definition, Drug Spend, Strategies, Cost Management, Utilization Management, Clinical Care Management, and Selecting a Provider. After completing this course, learners will be able to identify the major types of specialty pharmacy drugs and how they are administered to patients; recognize the costs of specialty pharmacy therapies and their impact on drug expenditures; recognize the difference in managing specialty drugs in the medical and drug benefit; identify strategies for controlling costs of specialty pharmacy drugs; identify approaches for managing utilization of specialty pharmacy drugs; and recognize the criteria for selecting a specialty pharmacy provider.

**Format**: eLearning - EduFlex, eLearning - SCORM

**Libraries**: Healthcare: General

**Functional Areas**: Healthcare: Specialty Pharmacy
Introduction to the Medical Device Single Audit Program (MDSAP)

This course covers the Medical Device Single Audit Program, which conducts audits of medical device manufacturers that satisfy the relevant requirements of five regulatory authorities participating in the program as well as those of ISO 13485:2016. Topics in this course include: Program, Audit Types, Structure, and Nonconformity Grading and Audit Responses. After completing this course, learners will be able to recognize the structure of the MDSAP as well as grading and follow-up requirements.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Medical Device GMPs
- Global Regulatory

**Functional Areas:**
- Medical Device

Languages Available:
- Portuguese (Brazil) (DEV62)
- French (European) (DEV62)
- Spanish (Spain) (DEV62)
- German (DEV62)
- Japanese (DEV62)
- French (Canadian) (DEV62)

Introduction to the Natural Gas Industry

Introduction to the Natural Gas Industry explains what natural gas is, why it is useful, and what it is used for. A brief description of the path of natural gas from the well to the customer is given along with a list of agencies responsible for pipeline regulations and the responsibilities of each pipeline employee to maintain safety and good environmental practices.

**Format:**

**Libraries:**
- DOT Operator Qualification - Oil And Gas Pipeline
- Midstream Topics

Introduction to the Quality System Regulation (QSR)

Good Manufacturing Practices (GMPs) help protect medical devices and medical device users. This course describes the GMPs for medical devices as specified in the Quality System Regulation (QSR). Topics in this course include: Quality System, Design Control, Software Validation, and Responsibility. After completing this course, learners will be able to identify the components of a quality system, design controls, and software validation.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**
- FDA Inspections and Enforcement
- Medical Device GMPs

**Functional Areas:**
- FDA QSR Basic Concepts
- Medical Device - GMP

**Partners:** FDA

**Content Bundles:**
- Medical Device - GMP

Languages Available:
- German (DEV43)
- French (European) (DEV43)
- Chinese (Simplified) (DEV43)
- Japanese (DEV43)
- Korean (DEV43)
- Spanish (Spain) (DEV43)

Introduction to the Regulation of Prescription Drug and Biologic Promotions

Promotional messages for prescription drugs are different from most commercial campaigns because the drugs, and the claims pharmaceutical companies make regarding their benefits, directly affect public health. The federal government regulates prescription drug and biologic promotions through organizations within the U.S. Food and Drug Administration (FDA). Topics in this course include: Regulation, Package Insert, General Requirements, Review Process, and Enforcement Actions. After completing this course, learners will be able to recognize how FDA defines promotional materials for prescription drugs and biologics. Learners will also be able to identify the organizations responsible for reviewing those materials as well as the general regulatory requirements with which promotional materials must comply.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Pharmaceutical - Sales & Marketing

**Functional Areas:**
- Pharmaceutical Sales Compliance
Introduction to Waste Management and Minimization

Introduction to Waste Management and Minimization provides general information about the management of solid waste, specifically hazardous waste as defined in RCRA Subtitle C, and an overview of the waste minimization hierarchy.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Investigating Pipeline Failure

Investigating Pipeline Failure explores the control of natural gas pipeline leakage and necessary leak investigation steps. DOT regulations for Continuing Surveillance and Investigation of Failure are also reviewed.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Investigational Product Development

This course provides an overview and summary of the investigational product development process. The course includes information on the different phases of clinical research necessary to file an Investigational New Drug Application (IND) and a New Drug Application (NDA). Topics in this course include: Stages, Trial Phases, Medical Devices, FDA Approval, and Post-marketing. After completing this course, learners will be able to recognize drug development phases and the main purpose of each phase as well as other elements of the investigational product development.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Clinical: Pharmaceutical

Functional Areas: GCP - Clinical Management

ISO 14155: Obligations of Sponsors and Monitors for Medical Device Trials

ISO 14155 is intended to be applied worldwide to clinical investigations of medical devices in order to fulfill the various national, regional, and international regulatory requirements. Topics in this course include: Ethics, CIP, Investigator's Brochure, Informed Consent, Other Documents, Sponsors, and Monitors. After completing this course, the learner will be able to identify the specific requirements of ISO 14155. The learner will also be able to recognize the roles and responsibilities of sponsors and monitors in clinical investigations of medical devices.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Clinical: Medical Device

Functional Areas: Clinical: Medical Device Topics

Languages Available:
Chinese (Simplified) (GCP20_SCH)
Japanese (GCP20_JP)
Korean (GCP20_KOR)
ISO 14971: Risk Management for Medical Devices
This course illustrates the application of risk management activities for medical device product safety through implementing the ISO 14971 International Standard for Risk Management. Topics in this course include: Overview, Definitions, General Requirements, Risk Assessment, Risk Control, Risk in Context, Risk Management File, and Tools. After completing this course, learners will be able to recognize how to apply risk management activities for medical device product safety.

Format: eLearning - SCORM, eLearning - EduFlex
Libraries: Medical Device GMPs
Functional Areas: ISO Standards

Isolators for Aseptic Processing
This course describes critical operating principles for the successful operation of an isolator for aseptic processing. Topics in this course include: Prepare, Leak Test, Decontaminate, Setup, Operate, Monitor, Clean, and Maintain. After completing this course, learners will be able to recognize the major process steps for isolator processing.

Libraries: Not specified
Functional Areas: Aseptic Processing
Programs: Aseptic Processing: Advanced Series

Japanese Medical Device and Pharmaceutical Regulations
The course introduces the Japanese medical device regulations. This course explores the scope and applicability of Japan's new Act on Medical Devices (PMD Act). Topics in this course include: History, Agencies, Approval Process, PMD vs ISO 13485, and Labeling. After completing this course, learners will be able to recognize the general structure of PMD and its requirements for the manufacture and distribution of medical devices to the Japanese market.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Global Regulatory
Functional Areas: Medical Device Market Entry

Job Performance Evaluations
Job Performance Evaluations examines differences between mentoring and job performance evaluations; the evaluator's role; employee evaluation plan; competency profiles; assessing knowledge, skills, attributes, and common barriers to accurate observation; teaching job task knowledge and job skills; and giving and receiving feedback.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics
Joining Steel Pipe Other Than by Welding

Joining Steel Pipe Other Than by Welding examines safety and environmental issues associated with joining pipe; determining correct thread length; application of sealing compound and tape; precautions for slip-type fittings; nut and bolt selection; tightening sequence and numbering systems for flange connections; reuse of a threaded fastener; calibration frequency, records, and specifications for torque wrenches; torque wrench maintenance; and abnormal operating conditions (AOCs).

Format:

Libraries:  
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Key Concepts of Process Validation

Production problems can result in high scrap rates, product failures, customer dissatisfaction, and even death of a user. This course identifies the key concepts in the regulatory requirements for the validation of manufacturing processes. Topics in this course include: Requirements and Procedures, Process Design, Verification and Validation, Installation and Operational Qualification, and Continued Verification and Revalidation. After completing this course, learners will be able to identify important aspects of process validation and identify the components of the validation life cycle.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Partners: FDA

Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- GMPs - Process Validation

Languages Available:
- German (PHDV77)
- French (European) (PHDV77)
- Chinese (Simplified) (PHDV77)
- Japanese (PHDV77)
- Korean (PHDV77)
- Spanish (Spain) (PHDV77)

Lab Safety

This course introduces the learner to the principles and practices that help make the laboratory a safe working environment. This course emphasizes the importance of developing a culture or philosophy of safe operations. Topics in this course include: Hazards, Laboratory Safety, Safe Practices, OSHA, and Training. After completing this course, you will be able to identify the types of hazards that make a laboratory unsafe and how to prevent or eliminate these hazards through compliance with safety regulations.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Partners: FDA

Libraries:
- Environmental Health and Safety

Functional Areas:
- GxP Basics

Languages Available:
- Spanish (Latin America) (PHDV67)

Laboratory Specimens for Clinical Research

This course will introduce you to regulations and guidelines that oversee the process of laboratory sample collection and shipping of human specimens for clinical research use in the United States. Topics in this course include: Clinical Laboratories, CLIA Certification, Site Responsibility and Documentation, Medical Waste Disposal, and Packaging and Transport of Specimens. After completing this course, learners will be able to identify the rules and regulations that apply to laboratory samples. In addition, learners will also be able to recognize how a sponsor utilizes the services of a central laboratory and how a principal investigator utilizes a local laboratory. Finally, learners will be able to identify the sponsor and investigator site responsibilities for collection of specimens, as well as specimen packaging for shipping.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Clinical-Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- GCP - Clinical Management

Languages Available:
- Spanish (Latin America) (GCP25)
Ladder Safety

Falls from ladders are one of the leading causes of workplace injuries and fatalities. Learning how to properly select and use a ladder will help prevent these accidents. Topics in this course include: Varieties of Ladders, Preparation for Ladder Use, Securing a Ladder, and Safe Use. After completing this course, learners will be able to recognize the varieties of ladders and how to prepare a ladder for use. Learners will also identify how to secure and safely use a ladder.

Format: eLearning - HIP2

Libraries:  
- Environmental Health and Safety

Functional Areas:  
- Workplace Safety

Lead

Lead exposure occurs during the production, use, maintenance, recycling, and disposal of lead materials and products. Topics in this course include: Hazards, Controls, Permissible Exposure Limits, and Monitoring. After completing this course, learners will be able to identify the acute and chronic effects of lead. Learners will also be able to identify the controls used to reduce lead exposure, and recognize the types of monitoring used to identify lead exposure.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:  
- Environmental Health and Safety

Functional Areas:  
- Workplace Safety

Leak & Pipeline Failure Investigation

Leak & Pipeline Failure Investigation addresses the importance of the control of pipeline leakage and proper steps of leak investigation necessary for the safe operation of any natural gas pipeline system. Applicable regulations, leaks in progress, special leak precautions, leak detection, and leak surveys are also examined.

Format:

Libraries:  
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:  
- Midstream Topics

Leak Survey & Leak Classification

Leak Survey & Leak Classification examines house counts, class locations, use of a "sliding mile," leak surveys and classification, pipeline patrols, pipeline marker installation, natural gas detection instruments, bar hole testing, natural gas migration patterns, leak survey records, and more.

Format:

Libraries:  
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:  
- Midstream Topics

Lean Six Sigma Case Study

Explore the key concepts of Lean Six Sigma with this dynamic case study featuring relatable examples of the methodology in action.

Format: eLearning - Other

Libraries:  
- Not specified

Functional Areas:  
- Lean Six Sigma
Lean Six Sigma Leadership and Improvement Teams
Learn the importance of the roles necessary to achieve a successful Lean Six Sigma implementation including the individual, team and leadership functions.

Format: eLearning - Other
Libraries: Not specified
Functional Areas: Lean Six Sigma

Lean Six Sigma Overview
A high-level overview of the concepts of Lean and Six Sigma.

Format: eLearning - Other
Libraries: Not specified
Functional Areas: Lean Six Sigma

Lean Six Sigma Principles and Core Methodologies
Examine the fundamental principles, key tools and core methodologies of Lean Six Sigma.

Format: eLearning - Other
Libraries: Not specified
Functional Areas: Lean Six Sigma

Line Stopping
Line Stopping defines line stopping and the regulatory requirements for performing a line stop. Other key topics include methods of locating and identifying the proper line, preparation considerations, and the steps of the line stopping process. Common abnormal operating conditions (AOCs) that may be encountered are listed, including possible responses.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Locating and Marking Buried Pipelines
Locating and Marking Buried Pipelines explains the requirements for locating and marking underground facilities before excavation work may take place. Common abnormal operating conditions (AOCs).

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics
Lockout/Tagout -- Affected

Accidents occur every year due to the release of uncontrolled energy during the maintenance and service of equipment or machinery in the workplace. Effective lockout/tagout procedures can prevent such accidents and protect employees during the service and maintenance of machines and equipment. This course focuses on affected employees who are required to participate in lockout/tagout procedures as part of their job. Topics in this course include: Types of Energy, General Requirements, and Lockout/Tagout Procedures. After completing this course, learners will be able to recognize the different types of energy and how they are controlled, who is involved in lockout/tagout, and the steps affected employees need to follow when participating in lockout/tagout procedures.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Environmental Health and Safety
Functional Areas: Workplace Safety

Lockout/Tagout -- Authorized

Accidents occur every year due to the release of uncontrolled energy during the maintenance and service of equipment or machinery in the workplace. Effective lockout/tagout procedures can prevent such accidents and protect employees during the service and maintenance of machines and equipment. This course focuses on authorized employees who lockout or tagout machines for service or maintenance. Topics in this course include: Types of Energy, General Requirements, Lockout/Tagout Procedures, and Energy Control Plan. After completing this course, learners will be able to identify various forms of energy and how they are controlled, who is involved in lockout/tagout procedures, the steps to take when performing lockout/tagout, and the key points of an effective energy control plan.

Format: eLearning - SCORM, eLearning - EduFlex
Libraries: Environmental Health and Safety
Functional Areas: Workplace Safety

LQ: Abnormal Operations

LQ: Abnormal Operations explores the difference between abnormal operations and abnormal operating conditions (AOCs) for liquids pipelines. This course also examines how to respond to, report, and record abnormal operations.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

LQ: Aboveground Storage Tank Overfill Protection

LQ: Aboveground Storage Tank Overfill Protection addresses the aboveground storage tank overfill protection program outlined by the American Petroleum Institute (API 2350). Also addressed are API and National Fire Protection Association (NFPA 30) recommended practices, overfill protection requirements and state regulatory agency impact, Class I liquids, overfill protection written procedures, product transfer written procedures, tank alarm levels and equipment for attended and unattended tank facilities, and abnormal operating conditions (AOCs).

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics
LQ: Below Ground Pipe Coatings & Exposed Pipe

LQ: Below Ground Pipe Coatings & Exposed Pipe addresses below-ground pipeline coating for hazardous liquid pipelines, remedial actions when exposed pipeline is located, pipe coating removal, pipeline operator responsibilities, marking exposed pipeline, pipe surface preparation, coating material preparation and application, jeeping, and abnormal operating conditions (AOCs).

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Cathodic Protection - Aboveground Storage Tanks

LQ: Cathodic Protection - Aboveground Storage Tanks addresses conditions for corrosion cell function, corrosion on metal structures, anodic and cathodic area functions and roles in protecting against metal loss on aboveground steel storage tanks, stray (interference) currents and direct current (DC), general and pitting corrosion, types of corrosion cells on steel storage tanks, galvanic (sacrificial) anodes and impressed current systems, external corrosion control testing intervals for cathodic protection systems and breakout tank inspections, insulated (electrical isolation) joints and protective coatings, anode operation and installation, measuring tank bottom-to-soil potential readings while considering the IR drop and at the center of the tank bottom, and abnormal operating conditions (AOCs) pertaining to rectifier inspections.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Cathodic Protection Troubleshooting

LQ: Cathodic Protection Troubleshooting examines cathodic protection rectifiers, including instruments used to troubleshoot rectifiers and cathodic protection systems; troubleshooting precautions and procedures; abnormal operating conditions (AOCs); common operational problems; rectifier repair techniques; basic troubleshooting techniques used when locating contacts; and abnormal operating conditions (AOCs).

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Conduct Annual Surveys

LQ: Conduct Annual Surveys examines pipeline safety regulations with regard to testing frequency of cathodically protected pipelines, including bonds and buried or submerged pipelines; measurement of tank bottom-to-soil, pipe-to-soil, tank bottom-to-soil, and casing-to-soil potentials; the electrical criteria used to determine adequate protection; electrode (half-cell); use of a multimeter while taking potentials reading; foreign electrical interference and foreign line interference testing; and handling abnormal operating conditions (AOCs) during annual surveys.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
LQ: Flushing and Purging Pipeline Systems

LQ: Flushing and Purging Pipeline Systems explains general guidelines for flushing and purging pipeline systems including preparation, flush solutions, soak times, vents and drains, depressurizing, pressurizing techniques, pigging, safety precautions, and training. Abnormal operating conditions (AOCs) relevant to flushing and purging are also discussed.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Inspecting and Testing Control Valves

LQ: Inspecting and Testing Control Valves explains the purpose of control valves in a pipeline system. The different parts that make up a control valve assembly and their functions are discussed. The process for inspecting a control valve is also explained. Common abnormal operating conditions (AOCs) that may be encountered while inspecting and testing control valves are identified, including preferred reactions.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Inspection - Aboveground Storage Tanks

LQ: Inspection - Aboveground Storage Tanks addresses tank shell inspections in accordance with API-575 Inspection of Atmospheric and Low-Pressure Storage Tanks; corrosion cell function; how corrosion occurs where electrical current leaves or flows from a metal structure; anodic and cathodic area functions and roles in protecting against metal loss on aboveground steel storage tanks; stray (interference) currents and direct current (DC); general and pitting corrosion; types of corrosion cells on steel storage tanks; applying cathodic protection; galvanic (sacrificial) anodes and impressed current systems; external corrosion control testing intervals for cathodic protection systems and breakout tank inspections; and abnormal operating conditions pertaining to rectifier inspections.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Installation of Anodes

LQ: Installation of Anodes addresses regulations regarding cathodic protection and test lead installation on liquid pipeline systems, terms associated with galvanic anode installation, the galvanic anode theory, types of anodes and their uses, calculations for sacrificial anode output and expected life, anode installation, cable bonding and exothermic welding techniques, and abnormal operating conditions (AOCs) during annual surveys.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
LQ: Installation of Test Stations

LQ: Installation of Test Stations addresses terms associated with exothermic welding procedures; test stations and cathodic protection regulations; test stations used for pipe-to-soil surveys; test station installation methods; performing pull tests; test station materials, spacing, and location; and recognizing and reacting to abnormal operating conditions (AOCs).

Format:

Libraries:

• DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:

• Midstream Topics

LQ: Interference (AC and DC)

LQ: Interference (AC and DC) addresses foreign interference; static, dynamic, and AC-induced stray currents; calculating circuit resistance of a bond; and eliminating stray current interference.

Format:

Libraries:

• DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:

• Midstream Topics

LQ: Introduction to Compressor and Pump Operations

LQ: Introduction to Compressor and Pump Operations explores the purpose, types, and basic functions of natural gas compressors and pipeline pumps; pump starting and stopping procedures; and the functions of the devices used to prevent pipeline overpressure, including relief valves, monitor regulators, regulators, pressure switches, and pressure transmitters.

Format:

Libraries:

• DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:

• Midstream Topics

LQ: Marking Pipelines - Temporary and Permanent

LQ: Marking Pipelines - Temporary and Permanent addresses key regulations for pipeline safety and corrosion control, including: excavation backfilling for liquid pipelines; location, installation, and maintenance of permanent pipeline marker signs; corrosion inspection for uncovered pipelines; continuing education; written damage prevention programs; one-call systems; responsibility for facility locations; temporary pipeline marking; symbols; qualifications to perform pipeline location and marking; excavation near pressurized pipelines; safety buffer zones; and abnormal operating conditions (AOCs).

Format:

Libraries:

• DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:

• Midstream Topics
LQ: Meter Maintenance and Proving

LQ: Meter Maintenance and Proving addresses metered volume, one of the primary and critical methods used in leak detection, by covering techniques employed in the overall practice of leak detection on liquid pipeline systems. This course also describes meter maintenance practices including meter proving, resetting meters following proving, and abnormal operating conditions (AOCs) that may be encountered while performing meter maintenance.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Pigging: Launching and Receiving

LQ: Pigging: Launching and Receiving is an introductory pipeline pigging course that explains the steps for launching and receiving pigs. It also examines operational considerations when pigging, including inspection and maintenance requirements for launcher and receiver closures, non-piggable pipeline options, pigging risks, and abnormal operating conditions (AOCs).

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Pipeline Patrol

LQ: Pipeline Patrol explains the methods of pipeline patrols, required inspections, and inspection intervals. Visual inspections include adequate pipeline cover, line markers and signs, exposed sections of pipelines, corrosion, crossings, changes in population, breakout tanks, and leak surveys. Electrical inspections include rectifiers and electrical insulators. Right-of-way maintenance is also discussed.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Pipeline System Control

LQ: Pipeline System Control explores the basic definitions of a liquid pipeline system, duties and responsibilities of a pipeline controller, types of pipeline control and their regulations, calculations on safe and timely product delivery, SCADA and SCADA monitoring systems, and procedure and follow-up actions for emergency response.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
LQ: Pressure Switches

LQ: Pressure Switches examines the functions of a pressure switch; absolute and gauge pressure; primary and secondary calibration standards; pressure switch inspection, operational testing, and calibration; federal regulations; and abnormal operating conditions (AOCs).

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

LQ: Pressure Testing Steel Pipelines

LQ: Pressure Testing Steel Pipelines explains the requirements for pressure testing steel pipelines. Some topics covered are water handling, pipe design, establishing MOP, pressure testing requirements, test preparation, and the pressure testing procedure. Abnormal operating conditions (AOCs) that may be encountered while pressure testing pipelines are identified, including possible responses.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

LQ: Pressure Transmitters

LQ: Pressure Transmitters examines pressure transmitter functions; absolute and gauge pressure; primary and secondary calibration standards; pressure transmitter inspection, operational testing, and calibration; documenting calibration results; applicable federal regulations; and abnormal operating conditions (AOCs).

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

LQ: Programmable Logic Controllers

LQ: Programmable Logic Controllers addresses the type of equipment the PLC replaces and the PLC application; functions of PLC hardware components; PLC modes of operation; PLC memory function; PLC installation in various environments; calibration and check-out of analog loops in a PLC, including zero and span adjustments; proper operation of discrete I/O in a PLC; documenting PLC calibration and check-out; basic troubleshooting; PLC ladder logic concepts and changes; PLC timers and counters, including function and on-site changes; adjusting PLC pressure set points on-site; implementing PLC programs on-site; documenting PLC program changes; and regulatory requirements for the use of PLCs in the pipeline industry.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics
LQ: Rectifier Inspections

LQ: Rectifier Inspections examines conditions for corrosion cell function, types of corrosion cells, requirements for liquid pipeline systems, controlling corrosion, cathodic protection testing, installation of test leads, cathodic protection rectifier inspections, and recognizing and reacting to abnormal operating conditions (AOCs).

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

LQ: Subpart H - Corrosion Control

LQ: Subpart H - Corrosion Control examines Corrosion Control regulations and other CFR Title 49 Part 195 provisions. Other topics include pipeline patrols; population changes and encroachments; underwater inspection and reburial of pipelines in the Gulf of Mexico; and inspection of exposed pipelines, right-of-way markers, in-service breakout tanks, and rectifiers.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Machine Safeguarding

Thousands of workers suffer serious injuries every year due to missing or improperly installed machine guards. These injuries can be prevented if proper safety precautions are in place. After completing this course, participants will be able to identify the basic requirements of machine safeguarding as well as different machine safeguarding techniques.

Format: eLearning - HiP2

Libraries:
- Environmental Health and Safety

Functional Areas:
- Workplace Safety

Languages Available:
Spanish (Spain) (EHS59-SP)

Maintaining and Repairing Pressure Limiting Devices

Maintaining and Repairing Pressure Limiting Devices explains the basic steps for maintaining pressure limiting devices, including spring-operated and pilot-operated relief valves, pressure switches, pressure transducers/transmitters, and monitor regulators. Abnormal operating conditions (AOCs) for maintaining and repairing pressure limiting devices are also included.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
Maintenance and Cleaning of Drug Manufacturing Equipment

Properly designed, constructed, cleaned, and maintained equipment lies at the core of the process control necessary to consistently manufacture pure, high quality drug products. In this course, you will learn about equipment selection, installation, qualification, and maintenance. After completing this course, you will be able to identify cleaning and maintenance practices for equipment used in manufacturing, as well as how a pharmaceutical company incorporates this equipment in their manufacturing. Additionally, you will be able to identify the necessary documentation and records for equipment used in the manufacture of prescription and over-the-counter drugs.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Languages Available:
- French (European) (PHA44)
- Japanese (PHA44)
- Spanish (Spain) (PHA44)

Partners: FDA

Making Ethical Decisions

The purpose of this training is to help you become a better decision maker when faced with ethics situations. You will recognize how to identify and resolve ethics issues and concerns, and you will identify how to get help when you are unsure as to the best course of action.

Format: eLearning - EduFlex, eLearning - SCORM

Making Meetings Work I: Purpose and Preparation

This course explores ways to assess the effectiveness of meetings and skills to enhance the meeting process. Topics in this course include: Purpose, Meeting Costs, Key Steps, and Prepare. After completing this course, learners will be able to recognize how to lead meetings, accomplish goals, and follow up to ensure success.

Format: eLearning - EduFlex, eLearning - SCORM

Making Meetings Work II: Leadership

The success of any meeting is largely determined by the leadership skills of the key participants. This course discusses the leadership skills necessary to conduct successful meetings. Topics in this course include: Start, Lead, Goals, Common Problems, Conflict, and Finish. After completing this course, learners will be able to recognize how to effectively set up, kickoff, conclude, and follow up a meeting. Learners should take Making Meetings Work I: Purpose and Preparation prior to taking this training.

Format: eLearning - EduFlex, eLearning - SCORM
Management of Change

Management of Change examines the concept of management of change (MOC), the types of changes, the application and importance of an MOC program, and the importance of understanding MOC processes used within a specific organization.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline
- Midstream Topics

Functional Areas:

Management Responsibility for Quality: What FDA Expects

Under FDA law and regulations, an effective and compliant Quality System literally begins and ends with management. This course explains who is considered management by FDA, what are management's responsibilities under FDA Good Manufacturing Practices, how FDA inspectors decide if management is meeting its obligations, and what are possible consequences if it is not. Topics in this course include: Authority, Quality System, Management Role, Quality Audits, Training, Outsourcing, and FDA Inspections. After completing the course, learners will be able to recognize how and why a successful Quality System depends on active management support and involvement to ensure safe and effective products reach patients and customers.

Format: eLearning - EduFlex, eLearning - SCORM

Languages Available:
- Chinese (Simplified) (PHDV101)
- French (European) (PHDV101)
- German (PHDV101)
- Japanese (PHDV101)

Libraries:
- Pharmaceutical GMPs
- Medical Device GMPs

Managing Conflict

As workforce numbers shrink, and individuals are called to interact more intensely with fewer people, the ability to manage conflict effectively becomes more important. This course identifies appropriate responses to conflict. Topics in this course include: Conflict Resolution Styles, Selecting Styles, Collaboration Guidelines, and Application. After completing this course, learners will be able to successfully approach and resolve conflict in the workplace.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management
- Professional Development

Managing Job Stress

Stress is a major factor in employee attendance, work performance, and Equal Employment Opportunity Commission (EEOC) claims. This course provides participants with an opportunity to assess their stress level at work and learn strategies for coping with that stress. Topics in this course include: Definition, Stressors, Positive Stress, Hassles, Outlook, and Visualization. After completing this course, learners will also be able to recognize strategies for coping with different problems in the workplace.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- HR Compliance & Risk Management
- Professional Development
Managing Transition to Teams

This course will help team leaders and team members to understand the process of moving from a hierarchical structure and mindset to a more team-oriented approach. Topics in this course include: Differences, Model, Transition, Vision, Coaching, and Example. After completing this course, learners will be able to recognize how to transition successfully from a top-down management approach to one in which team members work together to achieve greater results than could be achieved individually.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: HR Compliance & Risk Management
Functional Areas: Professional Development

MAO/PDP: Compliance Program Guidelines

Effective compliance programs are a requirement for Medicare Advantage Organizations (MAO) and Medicare Prescription Drug Plans (PDP) that contract to do business with the Centers for Medicare and Medicaid Services (CMS). This course describes how to properly design and implement an effective compliance program. Topics in this course include: General Requirements; Written Policies, Procedures, and Standards of Conduct; Compliance Officer, Committee, and High Level Oversight; Training and Education; Communication; Disciplinary Standards; Routine Auditing and Monitoring; and Prompt Response. After completing this course, learners will be able to recognize the requirements of an effective compliance program.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

MAPD/PDP: Communications and Marketing

This course examines what types of communication materials are regulated, what must be included in the materials and what is prohibited, how the CMS approval process works, the parameters of promotional marketing to beneficiaries, and what role providers and pharmacies are permitted to play in marketing a sponsor's plan. Topics in this course include: Definitions; Marketing Review Process and Required Documents; General Communication Requirements; General Marketing Requirements; Outreach Activities; Websites and Social/Electronic Media; Call Center Requirements; and Marketing and Sales Oversight. After completing this course, learners will be able to identify the communication materials that are regulated by CMS, the information that must be included in the materials, and how the CMS approval process works. Learners will also be able to identify what role providers and pharmacies are permitted to play in marketing a sponsor's plan.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

MAPD: Disenrollment

To ensure proper member disenrollment, specific standards must be maintained. This course describes processes and procedures for disenrollment from Medicare Advantage (MA) and Medicare Advantage-Prescription Drug (MAPD) health plans. Topics in this course include: Voluntary and Required Involuntary Disenrollments, Optional Involuntary Disenrollments: Non-Payment of Premiums, Optional Involuntary Disenrollment: Behavior, Post Enrollment Activities, and System Reports. After completing this course, learners will be able to identify the key concepts, principles, and the MA plan's responsibility in the disenrollment process.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Medicare Advantage
Functional Areas: Medicare Advantage
MAPD: Enrollment

To ensure proper member enrollment, specific standards must be maintained. This course describes processes and procedures for enrollment of beneficiaries into a Medicare Advantage (MA) and Medicare Advantage Prescription Drug (MAPD) health plans. Topics in this course include: Member Eligibility, Election Periods, Enrollment Mechanisms, Enrollment Process, and Auto and Facilitated Enrollments. After completing this course, learners will be able to identify the key concepts, principles, and the MA plan’s responsibility in the enrollment process, as well as identify requirements for submitting enrollment data.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Medicare Advantage

Functional Areas: Medicare Advantage

MAPD: Risk Adjustment and Data Validation

This course identifies the principles and motivation for risk adjustment of capitation payments that the Centers for Medicare & Medicaid Services (CMS) makes to Medicare Advantage (MA) plans. Topics in this course include: History, Goals, Hierarchical Condition Category (HCC), Documentation and Coding Requirements, Data Flow, and Data Validation. After completing this course, learners will be able to identify the components of the risk adjustment process, the requirements for data collection, and the process for submitting data to CMS.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Advantage

Functional Areas: Medicare Advantage

Markings and Accompanying Documents

Gain an understanding of the requirements of Clause 7 within IEC 60601-1 for markings, which address durability and legibility, markings on the outside of the equipment, markings on the inside of the equipment, markings of controls, safety signs, symbols, color of insulation, and indicator lights and controls.

Format: 

Libraries: Engineering Safety

Functional Areas: IEC 60601

Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation (Mass. Code) and Similar State-Level Requirements

The Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation (Mass. Code) imposes a number of restrictions on pharmaceutical and medical device manufacturing companies’ (including distributors’) interactions with healthcare practitioners. The Mass. Code is intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between pharmaceutical or medical device manufacturers and healthcare practitioners does not interfere with the independent judgment of healthcare practitioners. This course provides an introduction to the Mass. Code. Topics in this course include: Scope; Data; Contracts, Audits, and Meals; Education, Conferences, and Meetings; Other Payments, and Disclosure of Payments. After completing this course, learners will be able to recognize the provisions of the Mass. Code, 105 CMR 970.000, how to comply with new restrictions, and what some of the critical differences are between the Mass. Code and the AdvaMed and PhRMA Codes of Ethics.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medical Device - Sales & Marketing

Functional Areas: Vendor Credentialing
MDR Regulation 1: Overview and General Provisions

FDA investigators, compliance officers, medical device manufacturers, user facilities, and importers need to be aware of the Medical Device Reporting (MDR) regulation and its provisions. This course describes the key characteristics of the MDR regulation and its preamble as well as the key terms used in the MDR regulation. Topics in this course include: Origin, Device and Modernization Amendments, Characteristics, and Application. After completing this course, learners will be able to identify the key characteristics of the MDR regulation and its preamble as well as the key terms used in the MDR regulation. Also, you will be able to recognize to whom the MDR regulation applies and who is exempt from the regulation.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: 
- FDA Inspections and Enforcement
- FDA MDR
Functional Areas:
- FDA MDR
Partners: FDA
Languages Available:
- Chinese (Simplified)
- Japanese
- Korean

MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements

Medical device manufacturers, user facilities, and importers need to identify and monitor significant adverse events involving medical devices. This course describes important terms crucial to understanding the Medical Device Reporting (MDR) regulation and its requirements as they relate to user facilities, importers, and manufacturers. Topics in this course include: User Facilities, Importers, Manufacturers, and Event Files. After completing this course, learners will be able to identify the requirements for electronic MDR submission, MDR procedures, and event files.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: 
- FDA Inspections and Enforcement
- FDA MDR
Functional Areas:
- FDA MDR
Partners: FDA
Languages Available:
- Chinese (Simplified)
- Japanese
- Korean

MDR Regulation 3: Requirements for Individual Adverse Event Reports

FDA investigators, compliance officers, medical device manufacturers, user facilities and importers need to know how to document and submit adverse event reports in a timely fashion. This course identifies the proper forms and timelines for reporting adverse events. Topics in this course include: Reporting, MEDWATCH, Deadlines, Codes, and Exceptions. After completing this course, learners will be able to recognize the proper forms and timeframes necessary for adverse event reporting and identify when it is not necessary to file a report.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: 
- FDA Inspections and Enforcement
- FDA MDR
Functional Areas:
- FDA MDR
Partners: FDA
Languages Available:
- Chinese (Simplified)
- Japanese
- Korean

Mechanical Fittings

Mechanical Fittings examines Lycofit® fittings, joining plastic pipe with mechanical fittings, and installation of various kinds of couplings.

Format:
Libraries: 
- DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: 
- Midstream Topics
EGY-406MECH

T: 609.627.5300 | W: ulpoplearning.com | 202 Carnegie Center, Suite 301, Princeton, NJ 08540
Media Fills for Aseptic Processing

Media fills allow manufacturers to evaluate if their aseptic processes are capable of reliably producing sterile products that are free from contamination and are safe and effective for patients. This course describes the process of designing and executing media fills. Topics in this course include: Purpose and Design, Study Considerations, Execution, and Monitoring and Results. After completing this course, learners will be able to recognize the purpose of a media fill. Learners will also be able to identify the elements to consider while designing a media fill.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Aseptic Processing

Medical Device Filings: 510(k), PMA, and IDE

This course describes the premarket approval and notification processes for medical devices in the US. Topics in this course include: FDA Authority, Classification, Premarket Notification, Premarket Approval, IDE, and Compliance. After completing this course, learners will be able to identify the essential elements of the 510(k), premarket approval (PMA), and Investigational Device Exemption (IDE) filing processes for medical devices under FDA.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: Medical Device GMPs, Medical Device Market Entry

Medical Device Packaging, Labeling, and Distribution

Mistakes or mix-ups in the critical areas of product packaging, labeling, and distribution can pose a danger to the consumer. This course provides you with information on current packaging and labeling requirements specified by the Quality System Regulation. A basic understanding of quality system regulations for medical device and equipment manufacturers (21 CFR 820), quality control procedures, and quality principles are prerequisites for this course. Topics in this course include: Importance of Labeling, Packaging, Label Control, and Distribution. After completing this course, learners will be able to recognize the requirements for packaging, labeling, and distribution of medical devices 21 CFR 820.120-160.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medical Device GMPs, Quality Assurance

Medical Device Safety Reporting

This course explores the process by which US and European regulatory agencies ensure the safety of medical devices used in medical facilities and homes every day by following up on adverse events. Topics in this course include: Adverse Events, Premarket Reporting, Marketed Devices, and Reports. After completing this course, learners will be able to identify the regulatory requirements in the medical device clinical trial and postmarketing environments as well as recognize device safety monitoring and reporting efforts in the US and Europe.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Clinical-Medical Device

Languages Available:
- French (European)
- Spanish (Spain)
- German

Languages Available:
- French (European)
- Dutch
- Chinese (Simplified)
- Japanese

Languages Available:
- French (European)
- German
- Spanish (Spain)
Medical Education for Healthcare Professionals

Pharmaceutical companies contract with healthcare professionals to assist them in conducting market research, perform clinical trials, or endorse a product. The pharmaceutical industry has set forth certain guidelines that must be followed when engaging and providing medical education for healthcare professionals. This course discusses the various types of consulting arrangements that exist between a pharmaceutical company and healthcare professionals and the guidelines that govern these arrangements. It also explores the guidelines that impact medical education programs for healthcare professionals. Topics in this course include: General Guidelines, Consulting Arrangements, Medical Education Programs, Supporting Medical Education, and FDA and OIG Guidance on Medical Education. After completing this course, learners will be able to identify the various types of consulting arrangements that exist between a pharmaceutical company and healthcare professionals and the guidelines that govern these arrangements. Learners will also be able to recognize the guidelines that impact medical education programs for healthcare professionals.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Pharmaceutical - Sales & Marketing
- Functional Areas:
  - Pharmaceutical Sales Compliance

Medicare Advantage: Administration and Management

This course provides information on the administrative infrastructure and management capabilities required of all Medicare Advantage Organizations (MAOs). Topics in this course include: Basic Responsibilities, Basic Requirements, Specific Requirements, Infrastructure, and Documentation. After completing this course, learners will be able to recognize the critical role of management in operating an MAO, identify the basic administrative infrastructure necessary to do business with CMS in the Medicare Advantage (MA) program, and identify the areas where management must ensure compliance in the MAO.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Medicare Advantage
- Functional Areas:
  - Medicare Advantage

Medicare Advantage: Claims Processing

This course explores the Centers for Medicare and Medicaid Services (CMS) regulations and instructions for the processing of Part C medical claims for Medicare Advantage. Topics in this course include: Rules and Requirements, Benefits and Services, Payment (Claim) Organization Determinations, Claims Processing, and Enrollee Financial Caps. After completing this course, learners will be able to identify the Medicare Advantage plan's responsibilities in monitoring delegated claims processing.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:
- Medicare Advantage
- Functional Areas:
  - Medicare Advantage
Medicare Advantage: Grievances, Organization Determinations, and Appeals

The Medicare Part C program provides coverage for medical benefits for eligible Medicare beneficiaries. This course describes the grievance, organization determination, and appeal processes that are required in order to protect the rights of Medicare Part C enrollees. Topics in this course include: Representatives, Grievance Process, Organization Determinations, Reconsiderations, Discharge Appeals, Exceptions, Documentation and Reporting, and Education and Training. After completing this course, learners will be able to identify the definitions and regulatory requirements for processing grievances, organization determinations, and appeals including time limits, documentation, follow-up, and reporting procedures.

Instructions for handling Part D grievances, coverage determinations, and appeals are found in the course Medicare Part D: Grievances, Coverage Determinations, and Appeals.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: • Medicare Advantage

Functional Areas: • Medicare Advantage

Medicare Advantage: Membership Services

This course discusses the obligations of a Medicare Advantage Organization (MAO) and of the Centers for Medicare and Medicaid Services (CMS) regarding Member Services. Topics in this course include: Operations; MAO Operational Functions; Classification of Complaints, Appeals, and Grievances; Required Skills; and CMS Call Center Monitoring and Required Disclosures. After completing this course, learners will be able to identify an MAO’s Member Services functions, recognize CMS regulatory requirements related to Member Services, recognize the importance of classification of member complaints, and be aware of CMS’ call center monitoring process and member disclosure requirements.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: • Medicare Advantage

Functional Areas: • Medicare Advantage

Medicare Advantage: Overview of the Medicare Program

This course provides an overview of the Medicare Program including what it is, how it is implemented, and how government regulations influence it. This course also describes the Centers for Medicare and Medicaid Services (CMS), which is the agency responsible for developing and implementing Medicare policy. Topics in this course include: Medicare Population, Role of the Federal Government, CMS Structure and Function, Medicare Categories and Options, Medicare Advantage Plan, Payment Process, and Fraud and Abuse. After completing this course, learners will be able to recognize the Medicare coverage options and their eligibility requirements, the role of the Federal government in regulating Medicare, and the penalties for violating healthcare fraud and abuse laws.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: • Medicare Advantage

Functional Areas: • Medicare Advantage

Medicare Advantage: Plan Benefit Package and Bid Pricing Tool

This course covers benefits, plan benefit packages (PBPs), and tools for submitting bids. Topics in this course include: Benefits, PBP Design, PBP Tool, Bid Requirements, and Bid Pricing Tool. After completing this course, you will be able to identify how CMS defines a benefit, recognize how these benefits should be designed to create a PBP, recognize how to use the CMS system for submitting a PBP to CMS, identify who is required to submit a bid, identify what components are required for each bid, and recognize the elements of the Bid Pricing Tool.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: • Medicare Advantage

Functional Areas: • Medicare Advantage
Medicare Advantage: Provider Compliance

This course reviews requirements every provider must adhere to, including specific rights and responsibilities, and elements contained in their contract with the Medicare Advantage Organizations. Topics in this course include: Regulatory Requirements and Contract Provisions, Beneficiary Access to Care, Beneficiary Protections, Payment and Government Funds, Compliance Program, and Provider Rights. After completing this course, learners will be able to recognize the responsibilities of providers who contract with Medicare Advantage Organizations in order to be compliant with CMS’ regulatory requirements.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Medicare Advantage

Functional Areas: Medicare Advantage

Medicare Advantage: Provider Networks

This course examines provider networks and the tools associated with their development. It includes an in-depth look at tools that are used in the development and validation of provider networks, critical terms used by the Centers for Medicare and Medicaid Services (CMS), and the usefulness of template contracts and checklists, and credentialing and verification requirements. Topics in this course include: Provider Contracting, MAO Responsibilities, Network Adequacy, Qualification and Selection, and Credentialing Facilities. After completing this course, learners will be able to recognize CMS’ requirements for MA plans to provide adequate provider networks.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Advantage

Functional Areas: Medicare Advantage

Medicare Advantage: Quality Management and Utilization Management

This course describes the Quality Improvement (QI) regulatory requirements for a Medicare Advantage Organization (MAO). Topics in this course include: QI Program, QIP/CCIP Projects, QI Program Effectiveness, and Utilization Management (UM). After completing this course, learners will be able to identify the basics of implementing a QI program.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Medicare Advantage

Functional Areas: Medicare Advantage

Medicare Health Plan and PDP: Fraud, Waste, and Abuse

Healthcare fraud, waste, and abuse are considered a top priority to the US government, second only to terrorism and violent crime. This course addresses fraud, waste, and abuse laws, regulations, and guidelines that apply to Medicare health plans and Prescription Drug Plans (PDP) also referred to as plan sponsors. Topics in this course include: Background, Definitions, Government Oversight, and Data Reporting. After completing this course, learners will be able to recognize the increased government interest in managed care fraud and abuse including areas of concern and how to combat fraud, waste, and abuse.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Medicare Advantage, Medicare Part D

Functional Areas: Medicare Advantage
Medicare Part D: Administration and Management

This course describes the Medicare Part D program and details the requirements that companies must meet in order to become Medicare Part D sponsor organizations. This course examines the respective roles of CMS, state governments, the sponsor, and the sponsor's contractors. You will learn how sponsors can meet their regulatory obligation to demonstrate compliance with certain licensure and insurance-related provisions of state law in the states in which the sponsor plans to offer coverage.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Medicare Part D
Functional Areas: Medicare Part D

Medicare Part D: Bid and Benefit Package

This course explains the benefits available to individuals who are eligible for Part D and presents the requirements for bidding to become a sponsor. Topics in this course include: Standard Coverage, Alternative Coverage, Bid Requirements, Actuarial Requirements, and Bid Review Process. After completing this course, learners will be able to identify the requirements for successful bidding and recognize what CMS examines during the bid review process.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Medicare Part D
Functional Areas: Medicare Part D

Medicare Part D: Coordination of Benefits and True Out-of-Pocket Facilitation

This course examines the procedures required by the Centers for Medicare and Medicaid Services (CMS) that Part D sponsors (MAPDs and PDPs) must follow when coordinating benefits with other providers of prescription drug coverage. The course also discusses the Part D true out-of-pocket (TrOOP) facilitation process. Topics in this course include: Purpose, Sponsor Responsibilities, TrOOP Balances, and Claims Processing. After completing this course, learners will be able to recognize CMS' process for coordinating prescription drug benefits among payers and the requirement for calculating and maintaining accurate TrOOP information.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Medicare Part D
Functional Areas: Medicare Part D

Medicare Part D: Grievances, Coverage Determinations & Appeals

This course outlines the Centers for Medicare & Medicaid Services' (CMS) requirements for the grievances, coverage determinations, and appeals processes. Topics in this course include: Enrollee Protections, Grievances, Coverage Determinations, Exceptions, and Appeals. After completing this course, learners will be able to recognize the sponsors' obligations during the grievances, coverage determinations, and appeals processes. Learners will also be to identify the components of the grievance and appeals processes.

Format: eLearning (Editable) - CREATE, eLearning - EduFlex, eLearning - SCORM
Libraries: Medicare Part D
Functional Areas: Medicare Part D
Medicare Part D: Medication Therapy Management and Quality Improvement Program

This course identifies primary cost control provisions in detail, including drug utilization management (UM) and medication therapy management programs (MTMPs). Topics in this course include: Utilization Management, Formularies, MTMP: Services, MTMP: Beneficiaries, Quality Assurance, and Quality Improvement. After completing this course, learners will be able to identify primary cost control provisions, quality assurance requirements, and the processes CMS has implemented to conduct oversight of the primary cost control and quality provisions.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Medicare Part D

Functional Areas: Medicare Part D

Medicare Part D: PDP Disenrollment and Transaction Processing

The Medicare Part D program provides prescription drug coverage for eligible Medicare beneficiaries. This course describes processes and procedures for disenrollment from a Medicare Prescription Drug Plan (PDP). Topics in this course include: Disenrollment, Mistaken Enrollment/Disenrollment, and MAPx System. After completing this course, learners will be able to identify the procedures we must follow to disenroll members from our PDP. Learners will also be able to recognize the features of the processing system for PDP enrollment and disenrollment.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Part D

Functional Areas: Medicare Part D

Medicare Part D: PDP Enrollment

The Medicare Part D program provides prescription drug coverage for eligible Medicare beneficiaries. This course describes processes and procedures for enrollment in a Medicare Prescription Drug Plan (PDP). Topics in this course include: Member Eligibility, Enrollment Periods, Enrollment Mechanisms, Enrollment Process, and Auto and Facilitated Enrollment. After completing this course, learners will be able to identify the eligibility requirements individuals must meet in order to enroll in a PDP. Learners will also be able to recognize when people may enroll in PDPs, and what information our organization must collect and distribute prior to enrollment.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Part D

Functional Areas: Medicare Part D

Medicare Part D: Pharmacy Network

Part D sponsors must develop a network of pharmacies so beneficiaries have “convenient” access to drugs covered under Part D. Topics in this course include: Pharmacy Types, Access Requirements, and Contract Requirements. After completing this course, learners will be able to identify the types of pharmacies that can be included in a network as well as the requirements Part D sponsors must meet to contract with pharmacies and create a pharmacy network.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Part D

Functional Areas: Medicare Part D
Medicare Plan: Broker and Agent Training - Beneficiary Protections

This is course four in the required series of courses that must be taken by brokers and agents who are interested in marketing Medicare Part C and Part D products and Section 1876 Cost Contracts. This course describes the rights and protections of Medicare plan enrollees in Medicare Advantage Health Plans and Prescription Drug Plans (collectively referred to as Medicare plans in this course) as required by the Centers of Medicare and Medicaid Services (CMS), and the grievance, coverage determination and appeal processes that are required in order to protect the rights of Medicare plan enrollees. Topics in this course include: Basic Rights, Grievance Process, Organization Determinations and Appeals, Part D Determinations and Appeals, and Aggressive Marketing. After completing this course, learners will be able to identify the rights and protections available to Medicare beneficiaries in the Medicare Advantage (MA) and Part D programs. Learners will also be able to identify the grievance process and recognize the appeals process for Part C and Part D.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Broker/Agent Training

Functional Areas: Medicare Plan Broker Training

Medicare Plan: Broker and Agent Training - Broker/Agent Requirements

This course is the first of a series covering brokers and agents marketing and selling Medicare Part C and Part D products and Section 1876 Cost Contracts (collectively referred to as Medicare plans). Topics in this course include: Training, HIPAA, Compliance Program, and FWA. After completing this course, learners will be able to recognize specific requirements related to brokers/agents who want to sell Medicare plan products.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Broker/Agent Training

Functional Areas: Medicare Plan Broker Training

Medicare Plan: Broker and Agent Training - Marketing

This is course five in the required series of courses that must be taken by brokers and agents who are interested in marketing Medicare Part C and Part D products and Section 1876 Cost Contracts (collectively referred to as Medicare plans in this course). This module provides the rules related to marketing Medicare plan products as required by the Centers of Medicare and Medicaid Services (CMS).

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Broker/Agent Training

Functional Areas: Medicare Plan Broker Training

Medicare Plan: Broker and Agent Training - Medicare Basics

This is course two in the required series of courses that must be taken by brokers and agents who are interested in marketing Medicare Part C and Part D products and Section 1876 Cost contracts (collectively referred to as Medicare plans in this course). Topics in this course include: Medicare, MA Health Plans, Other Plan Types, Prescription Drug Coverage Plans, and Part D Utilization Management. After completing this course, learners will be able to identify the differences between Original Medicare, Medicare Advantage, and Medicare Prescription Drug options. Learners will also be able to recognize a few key attributes of the various product options. Lastly, learners will be able to identify who is eligible for various Medicare coverage options.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Broker/Agent Training

Functional Areas: Medicare Plan Broker Training
### Medicare Plan: Broker and Agent Training - Medicare Part C and Part D Enrollment & disenrollment

This is course three in the required series of courses that must be taken by brokers and agents who are interested in marketing Medicare Advantage Part D (MA-PD) plans, Prescription Drug Plans (PDPs), and Section 1876 Cost Plans. This module describes processes and procedures for enrollment and disenrollment from Medicare Advantage Health Plans and Prescription Drug Plans (collectively referred to as Sponsors in this course). Topics in this course include: Election Periods, Disenrollment, Enrollment Process, Processing the Enrollment Request, and Non-discrimination Requirements. After completing this course, learners will be able to recognize the responsibilities that the brokers and agents working with MA-PD plans, PDPs, and Cost Plans must meet when enrolling and disenrolling Medicare Advantage and Part D plan members.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:** Medicare Broker/Agent Training

**Functional Areas:** Medicare Plan Broker Training

### MedTech Europe Code of Ethical Business Practice

This course describes the MedTech Europe Code of Ethical Business Practice (the Code). Topics in this course include: General Criteria for Events, Specific Event Guidelines, Grants and Charitable Donations, Arrangements with Consultants, and Research. After completing this course, learners will be able to recognize the guidelines that apply to the many types of interactions between MedTech Europe members (Members or MedTech Members) and healthcare professionals (HCPs) and/or healthcare organizations (HCOs).

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Libraries:** Medical Device - Sales & Marketing

**Functional Areas:** Vendor Credentialing

**Content Bundles:** Corporate Compliance - Medical Device

### Meeting GMP Training Requirements

In order to produce products that are pure, safe, effective, and in compliance with FDA regulations, it is necessary to understand the nature of GMP Training Requirements. GMP regulations are very clear as to what training is required. This interactive program introduces you to these training requirements and asks you to apply them to actual FDA-regulated industry situations. Upon completion of this course, you will be able to discuss the requirements and different types of training specified in GMPs. You will also be able to discuss several varied approaches to training and understand the advantages and disadvantages of each. Finally, you will understand the more technical aspects of training, why each is important to GMP compliance, and identify examples of achieving training compliance.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Libraries:** Medical Device GMPs

**Functional Areas:** Pharmaceutical GMPs - Training

### Meeting Process Requirements for Returned and Salvaged Drug Products

Like any other product, pharmaceuticals may be returned from the marketplace for a variety of reasons, including overstock, mislabeling, or product defects. This course explains the unique principles and practices involved in proper handling and processing of returned and salvaged products. Topics in this course include: Definitions, GMP Regulations, Inspection, Harmful Conditions, and Product Details. After completing this course, learners will be able to recognize the procedures for correct handling of returned and salvaged pharmaceutical products.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:** Pharmaceutical GMPs

**Functional Areas:** Packaging, Warehousing and Distribution

**Partners:** FDA

Languages Available:
- French (European) (PHDV76)
- Chinese (Simplified) (PHDV76)
- Japanese (PHDV76)
Member Issue Classification — Part C

This course covers real-life scenarios and requires learners to apply knowledge of Medicare Advantage Organization (MAO) procedures in order to classify Part C member issues appropriately. Topics in this course include: Member Issues. After completing this course, learners will be able to identify the correct classification of member issues based on a brief summary of each situation.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Not specified

Member Issue Classification — Part D

This course covers real-life scenarios and requires learners to apply knowledge of procedures in order to classify member Part D issues appropriately. Topics in this course include: Member Issues. After completing this course, learners will be able to identify the correct classification of member issues based on a brief summary of each situation.

Format: eLearning - SCORM, eLearning - EduFlex
Libraries: Not specified

Member Issue Classification Training

This course provides an overview of the different types of member issues to provide Call Center, Appeals and Grievance, Utilization Management, and Pharmacy staff with guidance on how to appropriately classify the issues so that they are handled under the appropriate procedure(s). Topics in this course include: Importance, Types of Member Issues, Multiple Processes, and Copays. After completing this course, learners will be able to identify the key terms used by CMS related to inquiries, grievances, organization determinations, and appeals. Learners will be able to recognize the types of member issues that are classified in these categories. Learners will also be able to recognize how to apply this knowledge to member issues so they can be handled by the appropriate department.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Not specified

National Patient Safety Goals: HCIR Credentialing

This course focuses on best practices and safety goals for healthcare industry representatives (HCIRs). Topics in this course include: Definition, HCIR Program, What to Know, and Policies and Procedures. After completing this course, learners will be able to recognize the role and value of standardized credentialing training for HCIRs and the five substantive training areas recommended for HCIRs. Learners will also be able to recognize how this training advances the goals of safety, quality of care, confidentiality, and compliance with applicable regulatory guidelines.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Medical Device - Sales & Marketing
Functional Areas: Vendor Credentialing
Natural Gas Operations & Maintenance Safety

Natural Gas Operations & Maintenance Safety examines general safety precautions for natural gas operations and maintenance; testing for gaseous or oxygen-deficient atmosphere; lock-out and tag-out of gas valves; trenching and excavation safety guidelines; hazards of directional boring; traffic management, including traffic control zones; hazards of static electricity, including possible ignition; and the Hazard Decision Tree Analysis.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

NDT: Liquid Dye Penetrant Inspection

NDT: Liquid Dye Penetrant Inspection examines the liquid dye penetrant inspection process, including weld preparation, application of liquid penetrant cleaner and developer, weld post-cleaning, documentation requirements, and abnormal operating conditions (AOCs).

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

NDT: Magnetic Particle Inspection

NDT: Magnetic Particle Inspection explains the use of magnetic particle inspections (MPI) to detect cracks and other anomalies in a pipeline. There is heavy emphasis on the use of this process to detect stress corrosion cracking (SCC). It also explains the preparation methods and processes for performing a wet or dry magnetic particle inspection. Common abnormal operating conditions (AOCs) that may be encountered while inspecting a pipeline are identified, including preferred reactions.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Obligations of Investigators in Conducting Medical Device Trials

This course addresses the requirements for conducting clinical trials for investigational premarket medical devices. It provides an overview of the clinical investigator's general and specific obligations to protect human subjects while providing valid data that sponsors may submit to regulatory authorities for approval. This course also introduces documentation and reporting requirements, the inspection process, and the consequences for failure to comply with good clinical practice. It concludes with suggestions for improving compliance.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Clinical: Medical Device

Functional Areas: GCP Basics
Odorization: Concentration Testing

Odorization: Concentration Testing addresses natural gas odorization and its regulation, distribution systems, class determination, testing, recordkeeping, odometer operation and maintenance, and safe handling and storage.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Languages Available:
- Spanish (Latin America)

Office Safety

Hidden dangers lurk in every corner of a workplace. With potential hazards ranging from fire to personal injury, knowing how to identify hazards and avoid accidents can keep everyone safe in the office. This course identifies common hazards that may be present in your office and how to avoid such hazards. Topics in this course include: Emergency Action Plan, Hazard Identification, Safe Work Practices, Office Equipment, Walking Surfaces, Good Housekeeping, and Workplace Violence. After completing this course, learners will be able to describe an action plan, identify potential hazards in the workplace, and recognize methods of hazard avoidance.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:
- Environmental Health and Safety
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:
- Workplace Safety

Languages Available:
- Spanish (Latin America)

OIG Compliance Program Guidance for Medical Device Manufacturers -- Field Force

This course identifies practices that present a potential risk of liability for medical device manufacturers under the three major risk areas identified in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Topics in this course include: Risk Areas, Problematic Areas, Consulting Agreements, Truthful and Non-Misleading Product Promotion, and Discounting Arrangements. After completing this course, learners will be able to identify risk areas in medical device promotion as well as OIG Guidance for navigating these risks successfully.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Medical Device - Sales & Marketing

Functional Areas:
- Medical Device Sales Compliance

Languages Available:
- Spanish (Latin America) (PHA68)
- German (PHA68)
- French (European) (PHA68)
- Chinese (Simplified) (PHA68)
- Japanese (PHA68)

Operating Room Conduct

In your job, you may be asked to visit an operating room (OR) and assist with the setup or use of a medical device. This course addresses all aspects of operating room (OR) conduct and covers important, general information about the hospital environment and staff, proper behavior prior to and upon arrival at the hospital, and proper dress for the OR. Topics include: General Information, Protocols, Check-In Process, Attire, OR Setting, Representative Tasks, Considerations in the OR, and Hazards. After completing this course, learners will be able to identify proper operating room conduct.


Libraries:
- Medical Device - Sales & Marketing

Functional Areas:
- Vendor Credentialing

Partners: AORN

Languages Available:
- Spanish (Latin America) (PHA68)
- German (PHA68)
- French (European) (PHA68)
- Chinese (Simplified) (PHA68)
- Japanese (PHA68)

Languages Available:
- Spanish (Latin America) (PHA68)
- German (PHA68)
- French (European) (PHA68)
- Chinese (Simplified) (PHA68)
- Japanese (PHA68)
Operator Qualification Summary

Operator Qualification Summary discusses the development of an operator qualification program that is required of each pipeline company and summarizes the process for qualifying an individual to perform covered tasks.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Orientation to GMP Compliance

Because FDA GMP regulations have a direct impact on how you do your job, you need insight on how they are applied and interpreted. This course illustrates how the Food, Drug, and Cosmetic Act is tied to Title 21 of the Code of Federal Regulations and how Good Manufacturing Practices (GMPs) are key elements in those regulations. Topics include key definitions, GMP focus areas, interpretation of GMPs, and enforcement actions. After completing this course, you will be able to recognize GMP regulations, basic GMP requirements, your roles and responsibilities for compliance, and the ways FDA enforces GMP regulations.

Format:
eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- GMP Basic Concepts

Content Bundles:
- Pharmaceutical - GMP
- Medical Device - GMP

Languages Available:
- Spanish (Latin America) (PHDV73)
- German (PHDV73)
- French (European) (PHDV73)
- Dutch (PHDV73)
- Chinese (Simplified) (PHDV73)
- Japanese (PHDV73)

OSHA/DOT - Excavation Safety

OSHA/DOT - Excavation Safety explains basic excavation safety, excavation requirements, soil classification and testing, causes of cave-ins, and excavation protection. Abnormal operating conditions (AOCs).

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Overcoming Negativity in the Workplace

This course is designed to help learners manage and solve interpersonal conflicts at work or away from work. Topics in this course include: Viewpoints and Approaches, Evaluation, Changing Thoughts, Listening, and Application. After completing this course, learners will be able to identify the approaches and skills required to solve problems. Learners will also be able to recognize how to overcome negativity in the workplace.

Format:
eLearning - EduFlex, eLearning - SCORM

Libraries:
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:
- Professional Development
Overview of FDA's Bioresearch Monitoring Program

This is the first in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Nonclinical Laboratory, Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo Bioequivalence inspections. This course provides an overview and historical perspective of FDA's BIMO program.

Format: eLearning - HIP2

Partners: FDA

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical
- FDA BIMO Course Series

Functional Areas:
- Clinical: Quality Topics

Overview of the Clinical Research Process

Clinical research is the testing of experimental drugs, biologics, and medical devices in humans. This course describes the clinical research process for those who are involved in any aspect of the development, research, marketing, or sales of new drugs, biologics, and devices. Topics in this course include: Regulations, GCP, Documents, Phases, Timelines and Costs, and Final Stages. After completing this course, learners will be able to recognize the nonclinical and clinical components of new product development.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Languages Available:
- Chinese (Simplified) (GCP11)
- German (GCP11)
- Japanese (GCP11)

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- GCP - Clinical Management
- Global Clinical Operations

Content Bundles:
- Global Clinical Operations

Overview of the Preparation Requirements for the ICH Common Technical Document

This course is an overview of how completed research studies are organized and summarized to be in compliance with the International Conference on Harmonisation (ICH) Common Technical Document (CTD – M4) guideline. Topics in this course include: Organization, QOS, Nonclinical Sections, Clinical Sections, and Modules 3, 4, and 5. After completing this course, learners will be able to identify the purpose of the CTD and ICH recommendations for summarizing and reporting data for completed research studies. Learners will also be able to recognize where to find more detailed information about the recommended CTD format for the three primary scientific areas (Quality, Safety, and Efficacy) that are part of a CTD.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Clinical: Pharmaceutical

Functional Areas:
- ICH Common Technical Document

Oxygen/Acetylene Welding & Cutting

Oxygen/Acetylene Welding & Cutting addresses types of gas welding; identifying joints; equipment needed for oxy/acetylene and gas welding and cutting; neutral, carburizing, and oxidizing flames; purging hoses; field inspection of welds; weld positions; hot and cold welding and cutting; and safety precautions.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
Packaging and Labeling of Finished Pharmaceuticals

Proper packaging and labeling of pharmaceuticals insures safe and sufficient products for consumers. This course describes the packaging and labeling of pharmaceutical products. Topics in this course include: GMP Principles, Packaging, Consumer Protection, Precautions, Labeling, Label Control, and On-Line Controls. After completing this course, learners will be able to recognize GMP requirements for packaging and labeling and the systems and procedures that prevent mix-ups.

**Languages Available:**
French (European)
Spanish (Spain)
German
Japanese
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM
**Partners:** FDA

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Pandemic Preparedness: What Every Employee Should Know

Pandemic Preparedness: What Every Employee Should Know describes how pipeline employees and their workplaces can prepare for a pandemic, including how to protect themselves and adjust working arrangements to deal with a reduced workforce.

**Format:**

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Part 11: Electronic Records and Signatures -- Application

In many organizations today, electronic records and electronic signatures are becoming more common. This course identifies how to implement Part 11 and what it means in terms of FDA's enforcement policy for 21 CFR Part 11, Electronic Records; Electronic Signatures. Topics in this course include: Meeting Expectations, Records, Security, Electronic Signatures, System Documentation, and Audit Trails. After completing this course, learners will be able to recognize how to apply Part 11 regulations to your company's systems and records in accordance with FDA's expectations.

**Languages Available:**
French (European) (FDA61)
Chinese (Simplified) (FDA61)
Japanese (FDA61)
Korean (FDA61)

**Format:** eLearning - EduFlex, eLearning - SCORM
**Partners:** FDA

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Part 11: Electronic Records and Signatures -- Changes in Enforcement Policy

Since the inception of Part 11, FDA has issued changes to the enforcement policy for electronic records and signatures. This course describes how to implement the new changes of Part 11 enforcement. Topics in this course include: Key Changes, FDA Enforcement, and Unaffected Provisions. After completing this course, learners will be able to recognize FDA expectations for compliance with all applicable predicate rules.

**Languages Available:**
French (European) (FDA57)
Chinese (Simplified) (FDA57)
Japanese (FDA57)
Korean (FDA57)

**Format:** eLearning - EduFlex, eLearning - SCORM
Part 11: Electronic Records; Electronic Signatures

In many industries today, the use of electronic records and signatures is becoming more common. This course explains the purpose of 21 CFR Part 11. Topics in this course include: Records Requirements, Records Security, Electronic Signatures, Signature Controls, and FDA Enforcement. After completing this course, learners will be able to recognize how to properly implement and use an electronic record or signature. FDA requirements for computerized systems that generate electronic records ensure that they and any electronic signatures applied to them are trustworthy, reliable, and traceable to the person(s), events, and actions taken to generate the records.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:  
- FDA Inspections and Enforcement  
- Pharmaceutical GMPs

Languages Available:  
- French (European) (FDA31)  
- Chinese (Simplified) (FDA31)  
- Japanese (FDA31)  
- Korean (FDA31)

Personal Leadership Power

This course presents information about the definition of leadership, how to increase your PLP, and how to apply PLP to increase the productivity of your company. Topics in this course include: Leaders, Key Traits, Barriers, Personal Leadership Power (PLP), Five Principles, Developing Your PLP, and Workplace PLP. After completing this course, learners should be able to identify and apply the five principles involved in increasing and effectively using PLP for themselves and for their organizations.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:  
- Ethics & Corporate Responsibility  
- HR Compliance & Risk Management  
- Professional Development

Languages Available:  
- French (European) (EHS66-EF)

Personal Protective Equipment

Personal protective equipment (PPE) includes some of the items most frequently used to protect workers from hazards. Topics in this course include: General Requirements; Hazard Assessment; PPE for the Eyes, Face, and Head; PPE for the Body; and Maintenance. After completing this course, learners will be able to recognize the general and specific requirements for various types of PPE and methods for properly storing and maintaining PPE.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Environmental Health and Safety  
- EHS Basics

Languages Available:  
- French (European) (EHS67-EF)

Pharmaceutical and Medical Device Supplier Quality Management

A growing list of unsafe, counterfeit, contaminated, and defective products has emphasized the need for increased supplier quality management. This course discusses the regulations and standards for supply chain integrity. Topics in this course include: Origin, New Regulations, ICH Q10, Supplier Quality Agreements, and FDA vs EMA. After completing this course, learners will be able to recognize regulations and guidances, identify critical supplier quality agreements and audits, and recognize the differences between U.S. FDA and EMA approaches to supplier quality.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Medical Device GMPs  
- Pharmaceutical GMPs

Functional Areas:  
- GMPs - Suppliers

Partners: FDA
Pharmaceutical Risk Management: Picking the Right CAPA Tools

Any failure of a batch or its components to meet any of its specifications must be thoroughly investigated, whether or not the batch has already been distributed. This course describes the process of evaluating and using corrective and preventative actions (CAPA) systems and tools that align with an organization's methods and processes, so the Quality Assurance (QA) team can successfully determine which actions must be made to prevent future issues. Topics in this course include: CAPA Programs, Data Monitoring and Review, Analysis, and CAPA Software Tools. After completing this course, learners will be able to recognize the steps involved in the CAPA program. PHA40 Corrective and Preventive Actions is a prerequisite to this course and must be completed before taking this course.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: • Pharmaceutical GMPs

Functional Areas: • Pharmaceutical GMPs
- CAPA

Photography for FDA Enforcement

This course covers the legal requirements of photographing evidence for FDA investigators who take photographs for law enforcement purposes. It addresses FDA's authority to take pictures, and covers handling film and digital images, investigative techniques, the use of close-up photography, and the differences between 35 mm cameras and digital cameras.

Format: eLearning - HIP2

Libraries: • FDA Inspections and Enforcement

Functional Areas: • FDA Inspection Readiness

Physical and Network Security

Information security is critical for any business. This course identifies the types of assets that are at risk, outlines methods to protect them, and examines how every employee can develop a security mindset. Topics in this course include: The Security Mindset, Physical Security, Virtual Data Security, Use of the Internet, and Proprietary Information. After completing this course, learners will be able to recognize security risks to physical and virtual assets, identify their responsibilities for protecting all of these resources, and recognize requirements and guidelines for maintaining physical and network security.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: • Ethics & Corporate Responsibility

Functional Areas: • EHS - Physical Security
- Corporate Ethics

Physician Payment Sunshine Act

After completing this course, you will be able to recognize the meaning and purpose of the Physician Payment Sunshine Act. You will also be able to recognize key terms and phrases, such as, “applicable manufacturers,” “covered drug, device, biological, or medical supply,” “covered recipient,” and “payments or other transfers of value.” Lastly, you will be able to identify what needs to be reported, when it will be reported, how it will be reported, and the penalties for any failure to properly report.


Libraries: • Medical Device - Sales & Marketing
- Pharmaceutical - Sales & Marketing

Content Bundles: • Corporate Compliance - Pharmaceutical
- Corporate Compliance - Medical Device

Languages Available:
- French (European) (PHSM11)
- Spanish (Spain) (PHSM11)
- Chinese (Simplified) (PHSM11)
- German (PHSM11)
Pipeline Crossings

Pipeline Crossings addresses construction procedures, conditions, and special considerations involving natural gas pipelines at bridges, stream crossings, ravines, levees, highways and railroad crossings. External corrosion, control of buried or submerged pipelines, protective measures to control atmospheric corrosion, and use of electrical surveys, corrosion history reviews, and records of exposed pipe examinations are also discussed.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline

Pipeline Integrity: High Consequence Area Field Surveys

Pipeline Integrity: High Consequence Area Field Surveys discusses the description of class location units, class locations, DOT requirements, high consequence areas, and abnormal operating conditions (AOCs) that may be encountered.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline

Pipeline Pigging

Pipeline Pigging explores the reasons for pigging, pig types and use, common pigging techniques, safe launching and receiving practices, and smart pigging techniques.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline

Pipeline Purging With Air and Gas

Pipeline Purging With Air and Gas explains the mechanical nature of purging, isolation methods, and the processes of purging with either air or gas. Abnormal operating conditions (AOCs) that may be encountered while purging pipelines are also included.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline

Pipeline Repair: Composites

Pipeline Repair: Composites explains the use of composites to repair imperfections and damage on pipelines. Common abnormal operating conditions (AOCs) that may be encountered while making pipeline leak repairs are identified, including possible responses.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline
Pipeline Repair: Grinding, Welding, and Sleeving

Pipeline Repair: Grinding, Welding, and Sleeving explains the various types of pipeline leaks and the methods to repair them. The definitions and procedures for "hot" and "cold" cutting and welding are included. Common abnormal operating conditions (AOCs) that may be encountered while making pipeline leak repairs are identified, including possible responses.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: • Midstream Topics

Pipeline Repair: Sleeving Including Helical Pipe

Pipeline Repair: Sleeving Including Helical Pipe discusses various methods for pipeline repairs with the main emphasis on the fit-up procedure for weld-type sleeves over seamless, ERW, and helical pipe. Abnormal operating conditions (AOCs) that may be encountered are included.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: • Midstream Topics

Pipeline Security Planning

Pipeline Security Planning is not available.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: • Midstream Topics

Pipeline Shutdown and Startup Planning

Pipeline Shutdown and Startup Planning addresses steps to be taken during a planned shutdown, steps for returning a shut-down section to operation and starting up a new line, basic procedures for emergency shutdown, and how to prevent accidental ignition during shutdown and startup.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: • Midstream Topics

Pipeline Tie-in Methods

Pipeline Tie-in Methods is designed for gas transmission and distribution. This course addresses tie-in considerations regarding job planning, safety, equipment, materials and manpower; tie-in procedures, including line shutdown, purging, welding, pressure testing, required fittings, and returning the pipeline to service; tie-in configuration connections; and installation of one- and two-piece control fittings, steel-to-plastic transition fittings, curb and service valve tees, three-way tees, tapping and drilling, and stopping procedures for steel pipe.

Format:
Libraries: • DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: • Midstream Topics
Plastic Pipe Fusion

Plastic Pipe Fusion examines types of plastic pipe used in the heat fusion process, principles of heat fusion, the heat fusion process, inspection and testing of fused joints, safety precautions when handling polyethylene pipe, hazards of static electricity, and spark prevention.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Plug Valve Maintenance

Plug Valve Maintenance explains how a plug valve operates, along with many of the different design features and their purpose. It also discusses proper cleaning, lubricating, and maintenance techniques that are unique to plug valve maintenance. Common abnormal operating conditions (AOCs) that may be encountered while inspecting or maintaining valves are identified, including proper reactions.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Population Density Change & Pipeline Patrol

Population Density Change & Pipeline Patrol examines surveys for transmission, jurisdictional gathering, and distribution facilities; leak surveys and pipeline patrols; pipeline marker installation; house counts; natural gas detection instruments; marking exposed pipe; and more.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Postmarketing Reporting of Adverse Drug Experiences

This course explores the process for reporting postmarketing adverse drug experiences to FDA. Topics in this course include: Reports and Requirements. After completing this course, learners will be able to identify the process for reporting postmarketing adverse drug experiences to FDA.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Pharmaceutical - Sales & Marketing

Functional Areas:
- Pharmaceutical Sales Compliance
PPE Assessment

Thousands of workers suffer injuries each year. In many cases, these injuries could have been prevented by wearing appropriate personal protective equipment (PPE). Employers are required to assess the workplace and identify hazards which require the use of PPE, and to communicate this information to their employees, as well as provide them with the necessary protective equipment. Topics in this course include: Hazard Controls, Risk Analysis, Hazards, and Organization and Selection. After completing this course, learners will be able to recognize how to perform a workplace hazard assessment for PPE that covers what hazards to look for, how to collect and organize assessment data, how to estimate the level of hazard risk, and how to select the proper PPE for employees.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Environmental Health and Safety

Functional Areas:  
- EHS Basics

Pre- and Post-Approval FDA Drug Inspections

This course will explore pre-approval and post-approval FDA inspections. Specifically, the purpose and focus of each type of inspection will be discussed, along with the key inspectional targets of each. For pre-approval inspections, the discussion will primarily focus on the process and documentation related to demonstrating equivalence of the bio-clinical batches to the proposed commercial product. Key discussion points will include: evaluation of bio-clinical batches, raw materials, manufacturing process, finished product, and general GMP compliance. For post-approval inspections, the discussion will primarily focus on general GMP compliance issues. The various inspection outcomes for each type of inspection will also be covered. Because all FDA-regulated facilities will undoubtedly be subject to FDA inspection, it is important that employees understand what to expect and what their role should be. When this lesson is completed, the learner will be able to discuss the differences between pre- and post-approval FDA inspections, why they occur, and possible outcomes of each.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Pharmaceutical GMPs

Functional Areas:  
- FDA Inspection Readiness

Content Bundles:  
- GMP Inspection Readiness

Pressure Testing Plastic Pipelines

Pressure Testing Plastic Pipelines explains the requirements for pressure testing steel pipelines. Some topics covered are water handling, pipe design, class locations, MAOP, SMYS, strength testing, test preparation, and the pressure testing procedure. Common abnormal operating conditions (AOCs) that may be encountered while pressure testing pipelines are identified, including possible responses.

Format:

Libraries:  
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:  
- Midstream Topics

Pressure Testing Steel Pipelines - Gas

Pressure Testing Steel Pipelines - Gas explains the requirements for pressure testing steel pipelines. Some topics covered are water handling, pipe design, class locations, MAOP, SMYS, strength testing, test preparation, and the pressure testing procedure. Common abnormal operating conditions (AOCs) that may be encountered while pressure testing pipelines are identified, including possible responses.

Format:

Libraries:  
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:  
- Midstream Topics
Preventing Back Injuries

This course will provide information crucial to the identification, prevention, and treatment of back injuries and any associated complications.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Environmental Health and Safety

**Functional Areas:**
- Workplace Safety

**Languages Available:**
- German
- French (European)
- Chinese (Simplified)
- Japanese
- Spanish (Spain)

Preventing Sexual Harassment

You have a responsibility to yourself and your co-workers to take action when faced with sexual harassment in the workplace. This course describes workplace policies that ensure a harassment-free workplace. Topics in this course include: Definitions, Gray Areas, Taking Action, and Consequences. After completing this course, learners will be able to identify appropriate and inappropriate behavior as defined by the law and company policy.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**
- Ethics & Corporate Responsibility

**Functional Areas:**
- Harassment Topics

Prevention of Accidental Ignition & Potential Ignition Sources

Prevention of Accidental Ignition & Potential Ignition Sources examines the DOT rules governing accidental ignition sources of natural gas. Other topics include the fire triangle, common ignition sources for escaping natural gas, buildup and/or discharge of static electricity, hot and cold cutting and welding, and isolation of pipeline segments.

**Format:**

**Libraries:**
- DOT Operator Qualification - Oil And Gas Pipeline

**Functional Areas:**
- Midstream Topics

Principles of Aseptic Processing

Because microbiological and particulate contamination can potentially cause serious health problems in animals and humans, it is vital that sterile products be manufactured, filled, and packaged in an aseptic environment. This course will address the general principles and practices necessary to assure product sterility and safety related to aseptic processing. Topics in this course include: Cleanroom Requirements, The Process, Employee Practices, Validation, and Monitoring. After completing this course, learners will be able to recognize the general principles and practices necessary to ensure product sterility and safety, as well as the Good Manufacturing Practices (GMP) requirements for areas where aseptically produced products are handled.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Languages Available:**
- French (European) (PHDV71)
- German (PHDV71)
- Spanish (Spain) (PHDV71)

**Partners:** FDA

**Libraries:**
- Pharmaceutical GMPs

**Functional Areas:**
- Aseptic Processing

**Content Bundles:**
- Basics of Aseptic Processing
Principles of Auditing
This course focuses on the purpose and conduct of internal and external quality audits. Topics in this course include: Scope, Types of Audits, Benefits, Preparation, Performing Audits, and Audit Closeout. After completing this course, learners will be able to recognize the importance of an effective audit program, the benefits that can result, actual conduct of an audit, and how proper corrective action and follow-up yield the ultimate benefits of the program.

Languages Available:
Chinese (Simplified) (PHDV69)
Japanese (PHDV69)
Korean (PHDV69)

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM
Partners: FDA

Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- FDA Inspection Readiness
- GMP Inspection Readiness

Content Bundles:

Principles of Cleaning Validation
The cleaning of equipment used in a pharmaceutical operation can be a complex process. Even the smallest amount of chemical residual material in equipment can be extremely dangerous. This course will identify the basics of cleaning validation in pharmaceutical manufacturing operations. Topics in this course include: Cleaning Validation, Proper Cleaning Procedures, Assessing Cleanliness, Proving the Method, Acceptance Limits, Test Procedure, and Control and Monitor. After completing this course, you will be able to recognize why a cleaning Standard Operating Procedure is necessary. You will also be able to identify EU and FDA requirements for cleaning validation.

Languages Available:
German
French (European)
Spanish (Spain)

Format: eLearning - EduFlex, eLearning - SCORM
Partners: FDA

Libraries:
- Pharmaceutical GMPs

Functional Areas:
- Pharmaceutical GMPs - Cleaning Validation
- Basics of Aseptic Processing

Content Bundles:

Principles of Good Documentation
Documentation is an essential part of Good Manufacturing Practice (GMP). This course provides an overview for manufacturers of pharmaceutical and biological products of the documents required and the controls that should be in place. The regulatory requirements of FDA are addressed with reference also made to the requirements of the EU. The course provides an introduction to staff at all levels and highlights the personal responsibility they have for ensuring documentation is followed and documentation is correct.

Languages Available:
German (PHA74)
French (European) (PHA74)
Chinese (Simplified) (PHA74)
Japanese (PHA74)
Spanish (Spain) (PHA74)

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM
Partners: FDA

Libraries:
- Pharmaceutical GMPs
- Global Regulatory

Functional Areas:
- GMP Basic Concepts
- Pharmaceutical - GMP

Content Bundles:

Principles of Restricted Access Barrier Systems and Isolators
This course introduces the basic principles of two specific types of improved aseptic processing: Restricted Access Barrier Systems (RABSs) and isolators. Topics in this course include: RABS, Isolators, and Key Elements. After completing this course, learners will be able to recognize the basic attributes and functions of RABS and isolators, identify regulatory requirements for these systems, and recognize key elements of each type of system.

Languages Available:
French (European) (Aseptic03)
German (Aseptic03)
Spanish (Spain) (Aseptic03)

Partners: FDA

Libraries:
- Not specified

Functional Areas:
- Aseptic Processing

Programs:
- Aseptic Processing: Advanced Series
Principles of Sterilization

The success of sterilization can directly impact the quality and safety of products used by consumers. This course discusses the purpose of sterilization and basic principles of several commonly used sterilization techniques. Topics in this course include: Sterilization, Moist Heat, Dry Heat, Gas, Radiation, Chemical, Filtration, and Sterility Assurance. After completing this course the learner will be able to identify six types of sterilization, recognize methods for validating sterilization, and identify the key aspects of sterility assurance.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:  
- Medical Device GMPs  
- Pharmaceutical GMPs

Functional Areas:  
- Aseptic Processing

Content Bundles:  
- Basics of Aseptic Processing

Partners: FDA

Languages Available:  
- German (PHDV81)  
- French (European) (PHDV81)  
- Spanish (Spain) (PHDV81)

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Privacy and Data Protection

This course describes your responsibility for protecting any personal information that is under your control. Topics in this course include: Consequences, Personal Information, Laws, EU Regulations, and Reporting Problems. After completing this course, learners will be able to recognize what personal data must be protected according to the law and our company policies, as well as your personal responsibility in protecting this information. Learners will also be able to identify the risks involved in compromising personal data and know the basic guidelines for safeguarding it.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:  
- Ethics & Corporate Responsibility

Functional Areas:  
- Data Privacy

Content Bundles:  
- Corporate Compliance - Plan Sponsors  
- Corporate Compliance - General Industry

Languages Available:  
- German (ETHICS15)  
- Italian (ETHICS15)  
- French (European) (ETHICS15)  
- Chinese (Simplified) (ETHICS15)  
- Japanese (ETHICS15)  
- Portuguese (Brazil) (ETHICS15)  
- Spanish (Spain) (ETHICS15)  
- Turkish (ETHICS15)

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Process Gauge Radiation

Process gauges are found in chemical plants, refineries, and steel mills, and are one of many sources of industrial radiation. Process gauges measure the density of liquids, solids, levels within a vessel, and the thickness of solid materials. While they serve a useful function, their radioactive sources present a potential health hazard if not handled properly. Participants in this course will learn the uses of process gauges, along with the risks and safety regulations associated with process gauges.

Format: eLearning - HIP2

Libraries:  
- Environmental Health and Safety

Functional Areas:  
- Radiation Awareness

Languages Available:  
- German (EHS69)  
- Italian (EHS69)  
- French (EHS69)  
- Chinese (Simplified) (EHS69)  
- Japanese (EHS69)  
- Portuguese (Brazil) (EHS69)  
- Spanish (Spain) (EHS69)  
- Turkish (EHS69)

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Process Safety Management: Compliance Audits

Process Safety Management (PSM) is a regulation that requires companies to comply with 14 elements to reduce the risk associated with highly hazardous chemicals in process facilities. Compliance auditing is one of the fourteen elements and provides a way for companies to self-evaluate their implementation efforts. After completing this course, participants will recognize what a compliance audit is, what PSM elements are included in a compliance audit, and what steps should be taken to perform an effective audit. Before taking this course, participants should have completed Process Safety Management: Overview, Process Safety Management: Process Safety Information, Process Safety Management: Process Hazard Analysis, Process Safety Management: Management of Change, Process Safety Management: Operating Procedures, Process Safety Management: Mechanical Integrity Program, Process Safety Management: Pre-Startup Safety Review, Process Safety Management: Incident Investigation, Process Safety Management: Contractors, and Process Safety Management: Training.

Format: eLearning - HIP2

Libraries:  
- Environmental Health and Safety

Functional Areas:  
- Process Safety Management
Process Safety Management: Contractors
Many workers in process industries are contractors who perform maintenance or repair, turnaround, major renovation, or specialty work on or near a covered process. The Process Safety Management (PSM) regulation requires that both host employers and contractors work together to manage process safety. In this course, participants will learn the specific responsibilities both host and contract employers have for complying with the PSM regulation. Participants should have completed Process Safety Management: Overview, Process Safety Management: Process Safety Information, Process Safety Management: Process Hazard Analysis, Process Safety Management: Management of Change, Process Safety Management: Operating Procedures, and Process Safety Management: Mechanical Integrity before taking this course.

Format: eLearning - HIP2
Libraries: Environmental Health and Safety
   Functional Areas: Process Safety Management

Process Safety Management: Incident Investigation
Companies that are subject to the Process Safety Management (PSM) regulations are required to investigate each incident that resulted in, or could have resulted in, a catastrophic release of highly hazardous chemicals in the workplace. Investigating incidents and communicating incident reports internally ensures the proper corrective actions are implemented so that similar incidents do not occur in the future. In this course, participants will learn about the different types of incidents that must be investigated, when incidents should be reported, how to prepare incident reports, how to uncover root causes, and how to establish an effective system to implement corrective actions. Before taking this course, participants should have completed Process Safety Management: Overview, Process Safety Management: Process Safety Information, Process Safety Management: Process Hazard Analysis, Process Safety Management: Management of Change, Process Safety Management: Operating Procedures, Process Safety Management: Mechanical Integrity Program, and Process Safety Management: Pre-Startup Safety Review.

Format: eLearning - HIP2
Libraries: Environmental Health and Safety
   Functional Areas: Process Safety Management

Process Safety Management: Management of Change
Management of Change (MOC) is a program designed to identify, evaluate, and prevent chemical releases that could result from changes in processes, procedures, or equipment. This course covers the MOC requirements that are part of the PSM regulations. After completing this course, participants will be able to recognize how and when they must use an MOC procedure. They will also be familiar with the components of a successful MOC procedure. Before taking this course, participants should have completed Process Safety Management: Overview, Process Safety Management: Process Safety Information, and Process Safety Management: Process Hazard Analysis.

Format: eLearning - HIP2
Libraries: Environmental Health and Safety
   Functional Areas: Process Safety Management
Process Safety Management: Mechanical Integrity

EHS74

Inadequate mechanical integrity caused by unsafe process equipment can cause catastrophic events in chemical processing facilities. The Process Safety Management (PSM) regulation requires companies in the process industry to implement a Mechanical Integrity Program (MIP) to help prevent these catastrophic events. After completing this course, participants will know why a good MIP program is important. They will also be able to recognize the required elements of an MIP program and know how to maintain the mechanical integrity of a process. Before taking this course, participants should have completed Process Safety Management: Overview, Process Safety Management: Process Safety Information, Process Safety Management: Process Hazard Analysis, Process Safety Management: Management of Change, and Process Safety Management: Operating Procedures.

Format: eLearning - HIP2

Libraries:
- Environmental Health and Safety
- Process Safety Management

Process Safety Management: Operating Procedures

EHS75

Operating procedures are written instructions employees follow to safely perform their jobs in process operations. This course covers the operating procedure requirements that are part of the PSM regulations. After completing this course, participants will be familiar with operating procedures, be able to identify how operating procedures manage the risks and hazards associated with covered processes, and know how to develop operating procedures. Before taking this course, participants should have completed Process Safety Management: Overview, Process Safety Management: Process Safety Information, Process Safety Management: Process Hazard Analysis, and Process Safety Management: Management of Change.

Format: eLearning - HIP2

Libraries:
- Environmental Health and Safety
- Process Safety Management

Process Safety Management: Overview

EHS76

Languages Available:
Spanish (Latin America)

Unexpected releases of toxic, reactive, and flammable liquids and gases have caused great harm and numerous deaths. Such events underscore the need for better industry practices and safety management controls. This course introduces the structure of a process safety management (PSM) program for processes involving highly hazardous chemicals. Topics in this course include: Application of PSM, Elements of a PSM Program, and Employee Involvement. After completing this course, learners will be able to recognize the components of a PSM program, the companies and processes that fall under PSM regulations, and the importance of employee involvement in a PSM program. This is the first in a series of courses on process safety management.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Environmental Health and Safety
- Process Safety Management

Process Safety Management: Pre-Startup Safety Review

EHS77

Many companies have been cited for non-compliance with Process Safety Management violations. One of the most frequently cited is the lack of a Pre-Startup Safety Review (PSSR) when a new or modified system is introduced into a process. The participant in this course will learn what a startup is, what is involved with a PSSR, and how PSSRs are arranged, planned, and implemented. Before taking this course, participants should have completed Process Safety Management: Overview, Process Safety Management: Process Safety Information, Process Safety Management: Process Hazard Analysis, Process Safety Management: Management of Change, Process Safety Management: Operating Procedures, and Process Safety Management: Mechanical Integrity Program.

Format: eLearning - HIP2

Libraries:
- Environmental Health and Safety
- Process Safety Management
Process Safety Management: Process Hazard Analysis

Employers should perform appropriate Process Hazard Analysis (PHA) techniques in their workplace to ensure employee safety. This course describes Process Hazard Analysis techniques as part of the Process Safety Management (PSM) series. Topics in this course include, Preparing for a PHA, Risk Assessment, What-If and Checklist, HAZOP Method, FMEA Method, FTA Method, PHA Reports, and Implementation. After completing this course, learners will be able to identify what a PHA is and recognize the different types of PHAs a company can perform. Before taking this course, participants should have completed Process Safety Management: Overview and Process Safety Management: Process Safety Information.

Format: eLearning - HIP2

Libraries: • Environmental Health and Safety

Functional Areas: • Process Safety Management

Process Safety Management: Process Safety Information

In order to understand the hazards associated with a chemical process, documentation relating to the process must be gathered. This data provides the basis for developing process hazard analyses, preparing operating and maintenance procedures, training, performing incident investigations, and managing changes as they occur. This course introduces process safety information (PSI), a part of the Process Safety Management (PSM) series. In this course, the participant will learn what PSI is, the three main PSI categories, and what specific data is gathered within these categories.

Format: eLearning - HIP2

Libraries: • Environmental Health and Safety

Functional Areas: • Process Safety Management

Process Safety Management: Training

The root cause of many accidents can be traced back to inadequate communication and employee training. This course is part of the Process Safety Management (PSM) series and presents information on the training requirements for employees working in process industries. After completing this course, participants will be able to recognize the training requirements of the PSM regulations, what kind of training employers should provide, the different training methods that might be used, and how training should be documented. Before taking this course, participants should have completed Process Safety Management: Overview, Process Safety Management: Process Safety Information, Process Safety Management: Process Hazard Analysis, Process Safety Management: Management of Change, Process Safety Management: Operating Procedures, Process Safety Management: Mechanical Integrity Program, Process Safety Management: Pre-Startup Safety Review, Process Safety Management: Incident Investigation, and Process Safety Management: Contractors.

Format: eLearning - HIP2

Libraries: • Environmental Health and Safety

Functional Areas: • Process Safety Management

Promotion of Pharmaceutical Products -- Field Facing

This course outlines the guidelines, rules, and regulations that pharmaceutical companies must follow when promoting their products to healthcare professionals and consumers. Topics in this course include: Foundation, Promotion, Sales Representatives, Promotional Programs, and Non-Promotional Activities. After completing this course, learners will be able to recognize the guidelines for promoting products to healthcare professionals and consumers.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: • Pharmaceutical - Sales & Marketing

Functional Areas: • Pharmaceutical Sales Compliance
Promotion of Pharmaceutical Products -- In House


This course covers the guidelines, rules, and regulations that pharmaceutical companies must follow when promoting their products to healthcare professionals and consumers. Topics in this course include: Foundation, Advertising, Other Methods, Sales Representatives, Promotional Speaker Programs, and Non-Promotional Activities. After completing this course, learners will be able to recognize how these guidelines, rules, and regulations impact certain routine activities undertaken by pharmaceutical companies when promoting their products.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Pharmaceutical - Sales & Marketing
- Pharmaceutical Sales

Functional Areas:
- Compliance

Protection of Human Subjects in Clinical Trials

Languages Available:
- Chinese (Simplified)
- German
- Japanese

Protection of human subjects is the foremost and most important duty of investigators conducting clinical trials. This course will provide you with a working knowledge of informed consent regulations, Institutional Review Board/Independent Ethics Committee responsibilities, and the obligations of the individuals responsible for protecting patient rights and welfare. Topics in this course include: Consent Form, Consent Process, Consent Exceptions, IRB/IEC, and IRB/IEC Responsibilities. After completing this course, learners will be able to identify the measures that are in place to protect the rights and welfare of subjects in clinical studies. Learners will also be able to recognize informed consent requirements and regulations, the responsibilities of an IRB/IEC, and the obligations of individuals responsible for working according to GCP.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- GCP Basics

Partners: FDA

Protective Coatings

Languages Available:
- Chinese (Simplified)
- German
- Japanese

Protective Coatings explains basic corrosion, protective measures, corrosion regulations, surface preparation, and coating application. Abnormal operating conditions (AOCs) that may be encountered while inspecting and during the application of protective coatings are included.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
Public Awareness

Public Awareness addresses public awareness program requirements for the natural gas and hazardous liquids pipeline industries, including types of stakeholder audiences, message content, message delivery frequency, and program evaluation.

**Format:**

**Libraries:**
- DOT Operator Qualification - Oil And Gas Pipeline
- Midstream Topics

**Q10 Pharmaceutical Quality System**

This course describes a model for an effective quality management system for the pharmaceutical industry. The course is based on guidance developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is supported by the Food and Drug Administration (FDA) and is representative of their current thinking on this topic. Topics in this course include: Enablers, Management, Product Lifecycle, Process Performance, CAPA and Change, and Management Review and Improvement. After completing this course, learners will be able to recognize the approach to take in ensuring the pharmaceutical Quality System has the important principles needed to meet regulatory guidance. References: FDA Guidance for Industry “Q10 Pharmaceutical Quality System,” ICH, April 2009, 21 CFR Parts 210, 211, 600, and 606, Guidance for Industry, “Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations,” FDA, September 2006, Compliance Program Guidance Manual for FDA Staff: Drug Manufacturing Inspections, Program 7356.002, FDA, September 11, 2015, “Quality Systems for Drugs and Biologics,” Pharmaceutical Technology, February 2, 2008.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Global Regulatory
- ICH: Quality Management

**Q9: Quality Risk Management**

This course introduces the definition and principles of quality risk management (QRM) and the basic steps of a typical QRM process. Topics in this course include: QRM Process, Tools, and Applying QRM. After completing this course, learners will be able to identify the methodology and tools used in a risk management process.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Global Regulatory
- ICH: Quality Management

**QS Regulation 1: Overview and General Provisions**

This course introduces the Quality System (QS) Regulation (21 CFR Part 820) — a framework of basic requirements for manufacturers of finished medical devices. The course covers the history of the regulation, as well as its requirements, scope, and key terms. The course also discusses the manufacturer's responsibility for a quality system under this regulation. Topics in this course include: Origin, QS Regulation, Terms, Scope, and Responsibility. After completing this course, learners will be able to recognize the origin and scope of the QS Regulation. You will also be able to identify the purpose of the Preamble and general requirements of a quality system. Finally, you will be able to recognize key definitions.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Libraries:**
- FDA Inspections and Enforcement
- Medical Device GMPs
- FDA QSR Basic Concepts

**Content Bundles:**
- QSR for Medical Device Companies - Basics

**Languages Available:**
- Chinese (Simplified) (QSR01)
- Japanese (QSR01)
- Korean (QSR01)
QS Regulation 10: Servicing; Statistical Techniques

The Quality System (QS) regulation sets forth certain responsibilities for manufacturers relative to the servicing and statistical techniques requirements of the QS Regulation. This course is the tenth in a series of Quality System (QS) Regulation courses and focuses on Servicing (21 CFR Part 820 Subpart N) and Statistical Techniques (21 CFR Part 820 Subpart O). Topics in this course include: Key Terms, Analysis, Statistical Techniques, Preamble, and FDA Resources. After completing this course, learners will be able to recognize requirements for identifying valid statistical techniques.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: FDA Inspections and Enforcement, Medical Device GMPs
Functional Areas: FDA QSR Advanced Concepts
Content Bundles: QSR for Medical Device Companies - Advanced
Partners: FDA
Languages Available: Chinese (Simplified) (QSR10), Japanese (QSR10), Korean (QSR10)

QS Regulation 11: Application and Inspection of QS Regulation Requirements

The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. This course is the eleventh and final course in a series of Quality System (QS) Regulation courses. Topics in this course include: Key Terms, Seven Subsystems, Subsystems and QSIT, and Learn More. After completing this course, learners will be able to recognize the application and inspection of Quality System Regulation requirements within a medical device manufacturer's quality system.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: FDA Inspections and Enforcement, Medical Device GMPs
Functional Areas: FDA QSR Advanced Concepts
Content Bundles: QSR for Medical Device Companies - Advanced
Partners: FDA
Languages Available: Chinese (Simplified), Japanese, Korean

QS Regulation 2: Quality System Requirements

The second in a series of Quality System (QS) Regulation courses, this course focuses on the management responsibility, quality auditing, and personnel requirements of 21 CFR Part 820, Subpart B. The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Terms, Requirements, Structure, Management Representative, Management Reviews, Plan and Procedures, Audits, Personnel, and Preamble. After completing this course, learners will be able to recognize the QS Regulation requirements associated with a firm's management responsibility, quality auditing, and personnel.

Learners should complete QS Regulation 1: Overview and General Provisions before taking this course.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM
Libraries: FDA Inspections and Enforcement, Medical Device GMPs
Functional Areas: FDA QSR Basic Concepts
Content Bundles: QSR for Medical Device Companies - Basics
Partners: FDA
Languages Available: Chinese (Simplified) (QSR02), Japanese (QSR02), Korean (QSR02)
QS Regulation 3: Design Controls

Based on regulatory authority and findings that a significant portion of device recalls were attributed to faulty design, FDA included design control requirements in the Quality System (QS) Regulation. This course, the third in a series of Quality System Regulation courses, addresses design controls requirements of the Quality System Regulation. Topics include the design plan, the design review, verification, and validation. After completing this course, you will be able to recognize: the design control requirements of the QS Regulation; terms associated with design controls; and requirements for design control procedures. Learners should complete QS Regulation 1: Overview and General Provisions and QS Regulation 2: Quality System Requirements before taking this course.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: FDA Inspections and Enforcement, Medical Device GMPs
Functional Areas: FDA QSR Basic Concepts, Design Controls
Partners: FDA
Content Bundles: QSR for Medical Device Companies - Basics

Languages Available: Chinese (Simplified), Japanese, Korean

QS Regulation 4: Document and Purchasing Controls

The fourth in a series of Quality System Regulation (QS Regulation) courses, this course focuses on the document controls requirements of 21 CFR Part 820, Subpart D and the purchasing controls requirements of 21 CFR Part 820, Subpart E. The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Key Terms, Document Control, Evaluation & Selection, Records & Data, and Preamble. After completing this course, learners will be able to recognize the document and purchasing controls requirements of the QS Regulation.

Learners should complete QS Regulation 1: Overview and General Provisions, QS Regulation 2: Quality System Requirements, and QS Regulation 3: Design Controls before taking this course.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: FDA Inspections and Enforcement, Medical Device GMPs
Functional Areas: FDA QSR Basic Concepts
Partners: FDA
Content Bundles: QSR for Medical Device Companies - Basics

Languages Available: Chinese (Simplified) (QSR04), Japanese (QSR04), Korean (QSR04)

QS Regulation 5: Identification and Traceability; Production and Process Controls

The fifth in a series of Quality System (QS) Regulation courses, this course focuses on Identification and Traceability (21 CFR Part 820, Subpart F) and Production and Process Controls (21 CFR Part 820, Subpart G). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Identify and Trace, Production Processes, Controlling Changes, Other Controls, Software Validation, Equipment Calibration, and Process Validation. After completing this course, learners will be able to recognize a manufacturer's responsibilities relative to the Identification and Traceability requirements and Production and Process Controls requirements of the QS Regulation.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: FDA Inspections and Enforcement, Medical Device GMPs
Functional Areas: FDA QSR Basic Concepts
Partners: FDA
Content Bundles: QSR for Medical Device Companies - Basics

Languages Available: Chinese (Simplified) (QSR05), Japanese (QSR05), Korean (QSR05)
QS Regulation 6: Acceptance Activities; Nonconforming Product

The sixth in a series of Quality System (QS) Regulation courses, this course focuses on Acceptance Activities (21 CFR Part 820 Subpart H) and Nonconforming Product (21 CFR Part 820 Subpart I). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:
- FDA QSR Basic Concepts

Content Bundles:
- QSR for Medical Device Companies - Advanced

Languages Available:
- Chinese (Simplified) (QSR06)
- Japanese (QSR06)
- Korean (QSR06)

QS Regulation 7: Corrective and Preventive Action

The seventh in a series of Quality System (QS) Regulation courses, this course focuses on Corrective and Preventive Action (21 CFR Part 820 Subpart J). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics include: Key Terms, Investigate and Identify, Changes, Information, and Analyzing Data. After completing this course, you will be familiar with a manufacturer's responsibilities relative to the corrective and preventive action requirements of the QS Regulation. Learners should complete the previous courses in the series before taking this course.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:
- FDA QSR Advanced Concepts
  - Corrective and Preventive Actions (CAPA)

Content Bundles:
- QSR for Medical Device Companies - Advanced

Languages Available:
- Chinese (Simplified) (QSR07)
- Japanese (QSR07)
- Korean (QSR07)

QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution, and Installation

The eighth in a series of Quality System (QS) Regulation courses, this course focuses on Labeling and Package Control (21 CFR Part 820 Subpart K) and Handling, Storage, Distribution, and Installation (21 CFR Part 820 Subpart L). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Key Terms, Label Integrity, Labeling Operations, Handling/Storage Areas, Control & Distribution, and Device Installation. After completing this course, you will be able to recognize a manufacturer's responsibilities relative to the labeling, packaging control, handling, storage, distribution, and installation requirements of the QS Regulation.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:
- FDA QSR Advanced Concepts

Content Bundles:
- QSR for Medical Device Companies - Advanced

Languages Available:
- Chinese (Simplified)
- Japanese
- Korean
QS Regulation 9: Records
The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. This course, the ninth in a series of Quality System (QS) Regulation courses, focuses on Records (21 CFR Part 820 Subpart M). Topics include key terms, general requirements, Device Master Records, and investigations. After completing this course, you will be able to identify a manufacturer’s responsibilities relative to the records requirements of the QS Regulation.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:
- FDA QSAR Advanced Concepts

Content Bundles:
- QSR for Medical Device Companies

Languages Available:
Chinese (Simplified) (QSR09)
Japanese (QSR09)
Korean (QSR09)

QSIT 1 -- Beginning the Inspection
This is the first in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). This course provides guidance for inspecting medical device manufacturers against the Quality System Regulation, 21 CFR Part 820. Topics in this course include: Scope, Other Considerations, Sampling, and Reporting. After completing this course, learners will be able to recognize the purpose of QSIT during investigations of medical device manufacturers.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement

Functional Areas:
- FDA QSIT Inspection Readiness

Content Bundles:
- FDA QSIT Inspection Readiness

Languages Available:
Chinese (Simplified)
Japanese

QSIT 2 -- The Management Controls Subsystem
This is the second in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). This course will cover the Inspectional Objectives related to the Management Controls subsystem. Topics in this course include: Management Control Documents, Quality Policies and Objectives, Organizational Structure, Management Representative, Management Reviews, Quality Audits, and FDA 483. After completing this course, learners will be able to identify the seven Inspectional Objectives associated with the Management Controls subsystem.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement

Functional Areas:
- FDA QSIT Inspection Readiness

Content Bundles:
- FDA QSIT Inspection Readiness

Languages Available:
Chinese (Simplified)
Japanese

QSIT 3 -- The Design Controls Subsystem
This is the third in the a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). This course will explain the Inspectional Objectives associated with the Design Control subsystem as part of QSIT. The topics in this course include: Getting Started, Design Plan, Inputs and Outputs, Criteria/Verification, Design Validation I, Design Validation II, and Completion. After completing this course, learners will be able to identify each objective in the Inspectional Objective and ways to accomplish each objective.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement

Functional Areas:
- FDA QSIT Inspection Readiness

Content Bundles:
- FDA QSIT Inspection Readiness

Languages Available:
Chinese (Simplified)
Japanese
**QSIT 4 -- The Corrective and Preventive Actions Subsystem**

This is the fourth in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). The series provides guidance for inspecting medical device manufacturers against the Quality System Regulation, 21 CFR Part 820. Topics in this course include: Procedures, Problems, Received Data, Failure Investigations, Actions, and Documentation and Communications. After completing this course, learners will be able to identify the ten inspectional objectives associated with the CAPA subsystem and recognize the ways to accomplish those inspectional objectives.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- FDA Inspections and Enforcement

**Functional Areas:**
- FDA QSIT Inspection Readiness

**Partners:** FDA

**Content Bundles:**
- FDA QSIT Inspection Readiness

**Languages Available:**
- Chinese (Simplified)
- Japanese

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**QSIT 5 -- The Production and Process Controls Subsystem**

This is the fifth in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). The series provides guidance for inspecting medical device manufacturers against the Quality System Regulation, 21 CFR Part 820. Topics in this course include: Selection, Control and Monitoring, Operating Limits, Validation, Software, and Personnel. After completing this course, learners will be able to recognize the inspectional objectives related to the Production and Process Controls subsystem.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- FDA Inspections and Enforcement

**Functional Areas:**
- FDA QSIT Inspection Readiness

**Partners:** FDA

**Content Bundles:**
- FDA QSIT Inspection Readiness

**Languages Available:**
- Chinese (Simplified)
- Japanese

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**Quality Management Refresher**

All firms must understand how to deliver products and services of high quality to remain competitive. In the end, quality management is not about buzzwords and labels; it is about performance, competitiveness, and customer satisfaction. This course presents refresher information about the fundamental ideas, principles, and tools of quality management. It assumes that basic quality practices are already in place, and is designed to help keep firms on track in their quality management practices.

**Format:** eLearning - HIP2

**Libraries:**
- HR Compliance & Risk Management

**Functional Areas:**
- Process Safety Management

**Languages Available:**

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**Quality Systems Approach**

This course explains FDA's guidance on a modern quality systems approach to pharmaceutical manufacturing. Topics in this course include: FDA's Approach, Quality Concepts, FDA Compliance, Quality System Model, Management Responsibilities, Resources, Manufacturing Operations, and Evaluation Activities. After completing this course, learners will be able to identify the guidance that FDA has provided on quality systems, the ways in which this supports cGMP compliance, and the ways in which the application of a quality systems approach encourages the use of modern quality management principles and promotes innovation and continuous improvement.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Global Regulatory

**Functional Areas:**
- ICH: Quality Management
Quality Systems Inspection Technique (QSIT)

Manufacturing companies within the biomedical industry are subject to routine inspections of their quality systems by FDA. This course describes an FDA Quality System inspection by explaining the key objectives that an investigator will address when reviewing each subsystem. Topics in this course include: Procedure, Management Controls, Design Controls, Corrective and Preventive Actions (CAPA), Production and Process Controls (P&PC), and Preparation. After completing this course, learners will be able to identify the key elements for meeting the Quality System Regulation requirements.

Format: eLearning - SCORM, eLearning - EduFlex
Libraries: FDA Inspections and Enforcement
Functional Areas: Quality Assurance
Content Bundles: FDA QSIT Inspection Readiness
Partners: FDA
Languages Available: French (European), Chinese (Simplified), Japanese, Korean

RABS for Aseptic Processing

Restricted Access Barrier System (RABS) technology was developed to remove operators from the critical processing zones during sterile product manufacturing. This course describes key features and critical operating principles of a RABS used for aseptic processing. Topics in this course include: Prepare, Leak Test, Disinfection, Setup, Operate, Monitor, Clean, and Maintain. After completing this course, learners will be able to identify the key benefits of RABS for aseptic processing, and identify methods for material transfer with a RABS unit.

Format: eLearning (Editable) - CREATE, eLearning - EduFlex, eLearning - SCORM
Libraries: Not specified
Functional Areas: Aseptic Processing
Programs: Aseptic Processing: Advanced Series
Languages Available: French (European) (Aseptic05), German (Aseptic05), Spanish (Spain) (Aseptic05)

Recalls of FDA Regulated Products

The monitoring of recalls of potentially hazardous consumer products is one of the most important activities performed by FDA personnel. This course explores the basics of product recalls and personnel responsibilities during recall situations. Topics in this course include: Purpose and Types, Causes, Classifying Recalls, Responsibilities, and Audit Check. After completing this course, learners will be able to recognize FDA's definition of a product recall; recognize the contents of a recall letter; identify the types, depth, and classification of a recall; and recognize the responsibilities of FDA personnel during a product recall.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM
Libraries: FDA Inspections and Enforcement
Functional Areas: FDA Inspection Readiness
Partners: FDA

Reciprocating Compressor Units

Reciprocating Compressor Units addresses operation of an internal combustion-reciprocating compressor, including start-up, loading, unloading and shutdown procedures; parts of a compressor; and compressor troubleshooting and maintenance.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics
Languages Available: French (European) (EGY-701RECIP), German (EGY-701RECIP), Spanish (Spain) (EGY-701RECIP)
Recognizing and Avoiding Conflicts of Interest

This course provides an overview of conflicts of interest, and also provides guidance and reporting mechanisms for conflicts of interest. Learners will be able to recognize the circumstances that can cause actual or potential conflicts of interest, and also recognize the steps to take to avoid these conflicts or to properly disclose them when they occur.


Libraries: Ethics & Corporate Responsibility

Functional Areas: Corporate Ethics

Content Bundles:
- Corporate Compliance - Pharmaceutical
- Corporate Compliance - Medical Device
- Corporate Compliance - Plan Sponsors
- Corporate Compliance - General Industry

Languages Available:
- Italian (ETHICS11)
- French (European) (ETHICS11)
- Chinese (Simplified) (ETHICS11)
- Japanese (ETHICS11)
- Spanish (Spain) (ETHICS11)

Recognizing and Avoiding Insider Trading

This course will identify common situations that violate insider trading laws. Topics in this course include: Recognizing Inside Information and Insider Trading Situations. After completing this course, learners will be able to recognize what constitutes inside information, and how to recognize common insider trading violations.


Libraries: Ethics & Corporate Responsibility

Functional Areas: Ethics Basics

Recruitment and Retention of Study Patients

This course will discuss recruitment and retention of volunteers within a clinical trial. Topics in this course include: Pre-recruitment, Recruitment, Recruiting Methods, Special Populations, and Enrollment & Retention. After completing this course, learners will be able to identify acceptable ethical and regulatory recruitment and retention methods that can be used for clinical research trials and recognize key factors in recruiting and retaining subjects.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: Corexcel

Libraries: Clinical: Medical Device

Functional Areas: GCP Basics

Regulatory Requirements for Medical Devices in the Republic of Korea

This course covers the regulatory framework for medical devices in the Republic of Korea, recent and upcoming regulatory changes, and the medical device market in the Republic of Korea.

Format: eLearning - SCORM, eLearning - EduFlex

Languages Available:
- Korean

Libraries: Global Regulatory

Functional Areas: Medical Device Market Entry
Reporting Adverse Events for Medical Devices

This course introduces the process for filing medical device reports (MDRs) for adverse events and identifies the different types of reports used.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Medical Device - Sales & Marketing

Functional Areas: Vendor Credentialing

Content Bundles: Vendor Credentialing

Requirements for Computerized Systems Validation and Compliance

This course, the first in a four-part series, describes regulatory requirements and expectations regarding the validation and compliance of computerized systems used in the manufacture of pharmaceuticals, biologicals, and medical devices. It does not cover the detailed requirements of 21 CFR Part 11, except for the requirement that systems be validated. Even though it draws upon medical device guidance, it is not intended to cover all the requirements of producing software that subsequently becomes part of a medical device.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Medical Device GMPs, Pharmaceutical GMPs

Functional Areas: Computer Systems Validation

Content Bundles: Computer Systems Validation

Languages Available:
- German (PHDV102)
- French (European) (PHDV102)
- Chinese (Simplified) (PHDV102)
- Japanese (PHDV102)
- Korean (PHDV102)
- Spanish (Spain) (PHDV102)

Resolving Out Of Specification Test Results

Obtaining an out of specification test result can be unsettling, and it is important that you know what to do with it. This course will provide you with the information to respond accordingly when an OOS result is encountered. Topics in this course include: Phase One, Phase Two, Averages, Outliers, and Failure Investigations. After completing this course, learners will be able to recognize what to look for and what to investigate when an OOS result occurs.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medical Device GMPs, Pharmaceutical GMPs

Functional Areas: Pharmaceutical GMP Basics

Partners: FDA

Languages Available:
- Chinese (Simplified)
- Japanese

Respiratory Protection

Low oxygen levels and air contamination (e.g., hazardous particulates, gases, vapors) can threaten the health of a person's respiratory system. Training in the proper use of respiratory protection equipment saves many lives each year. In this course, participants will learn the types of respiratory hazards in the workplace and the respiratory protection equipment that can protect them from each hazard. Participants will also learn proper selection, use, maintenance, and storage for this equipment as well as the key elements of an effective respiratory protection program.

Format: eLearning - HIP2

Libraries: Environmental Health and Safety

Functional Areas: EHS Basics

Languages Available:
- Chinese (Simplified)
- Japanese
Respiratory Protection Awareness (US)

Inhalation is the most common way chemicals enter the body. Therefore, understanding and complying with the OSHA Respiratory Protection Standard could prevent hundreds of deaths and thousands of illnesses annually. This training will present the basic requirements of the respiratory protection program and will focus on the types and limitations of respirators.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Review of Basic Statistical Techniques

The use of statistics in medical device manufacturing is now expected and regulated by the Food and Drug Administration in the Quality System Regulation, Subpart O, “Statistical Techniques.” This course describes the proper use of statistical techniques as they apply to medical device manufacturing. Topics in this course include: Data Analysis, Histograms, and Variability. After completing this course, learners will be able to recognize how to interpret data using basic statistical techniques.

Format: eLearning - SCORM, eLearning - EduFlex
Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Rigging: Planning and Inspections

Rigging: Planning and Inspections explains the planning of a rigging operation, basic math needed for weight calculations, equipment used in rigging, and inspections for rigging equipment.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Right-of-Way Agent Training: Landowner Communications

Right-of-Way Agent Training: Landowner Communications examines best practices for communicating with landowners whose properties may be affected by pipeline construction, including the operator’s commitments to the landowners.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline
**Risk Management 1: Key Concepts and Definitions**

FDA manages risk in an attempt to prevent loss or injury by ensuring their medical devices, human and veterinary drugs, food additives, biologics, or other products are safe. This course focuses on Risk Management as it applies to FDA and its regulated industries. This course is also designed to provide an understanding of Risk Management as defined by the International Organization for Standardization (ISO). Topics in this course include: Risk, Calculating Risk, Safety, and Managing Risk. After completing this course, learners will be able to recognize the key concepts and definitions associated with risk management.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Libraries:**
- FDA Inspections and Enforcement

**Functional Areas:**
- Risk Management

**Partners:** FDA

**Languages Available:**
- Chinese (Simplified) (FDA29)
- Japanese (FDA29)
- Korean (FDA29)

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**Risk Management in Pharmaceutical Manufacturing**

This course covers the practical application of risk management principles, published in "Guidance for Industry: Q9 Quality Risk Management", through case studies applied to process design and manufacturing. Topics in this course include: Risk Assessment, Risk Control, Review and Communication, Validation Case Study, and Change Control Case Study. After completing this course, learners will be able to recognize risk management principles for the pharmaceutical industry and the tools that can be used to reduce patient risk and ensure quality throughout a product's lifecycle.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Pharmaceutical GMPs

**Functional Areas:**
- Pharmaceutical GMPs - Basics

**Content Bundles:**
- Pharmaceutical - Risk Management

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**Role of IEC 60601 Around the World**

Gain a high-level understanding of how the IEC 60601 series and the IECEE CB Scheme are used to demonstrate compliance with regulatory requirements worldwide.

**Format:**

**Libraries:**
- Engineering Safety

**Functional Areas:**
- IEC 60601

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**Role of the Qualified Person**

The role of the Qualified Person (QP) is defined in European Union legislation. This course explains the release of medicinal products to the market, the release of clinical trial materials, and pharmacovigilance. Topics in this course include: Regulation, Qualifications/Codes of Practice, Batch Certification, Different Supply Situations, Clinical Trials, and Pharmacovigilance. After completing this course, learners will be able to identify the role and responsibilities of both types of QP defined in EU legislation.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Medical Device GMPs
- Pharmaceutical GMPs

**Functional Areas:**
- GMP Pharmaceuticals - EU Regulations

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**Safe Driving**

This course provides critical information on pre-trip safety inspections, highway, city, and town driving, how to drive in inclement winter weather, and impairments that can affect your safety while driving.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**
- Environmental Health and Safety

**Functional Areas:**
- Workplace Safety
Safe Rigging Practices

Safe Rigging Practices explains the proper use of rigging equipment, hoists, and standard hand signals for rigging operations.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Safeguarding Intellectual Property

This course discusses how to identify and protect the Intellectual Property (IP) assets of a company. It also covers the four primary types of intellectual property with which a company deals. This course explores the business, ethical, and legal consequences of violating IP laws and protections, and an individual's responsibility for safeguarding the IP of a company and that of others.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- Ethics & Corporate Responsibility

Functional Areas:
- Intellectual Property

Safety Signs and Color Codes

Being able to recognize and understand safety signs and color codes are essential in performing work safely, effectively, and efficiently. This course describes safety signs, color codes, and tags that are used to indicate important information or identify hazards found in your workplace. Topics in this course include: Signs, Color Codes, Tags, Directional Signage, and Hazardous Substances. After completing this course, learners will be able to recognize signs and colors that identify hazardous substances in the workplace.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:
- Environmental Health and Safety

Functional Areas:
- Safety Awareness

Sample Collection

This course explores sample collection as a critical responsibility of field personnel. It explains the purpose of sampling and covers how to properly perform sampling. Topics in this course include: Purpose, Types, Preparation, Size, Techniques, Conduct, Submission, and Sample Validity. After completing this course, learners will be able to recognize the reasons for collecting and maintaining samples, identify the major samples types, and identify the differences between domestic and import samples. Learners will also be able to recognize how to prepare and conduct proper sampling and identify the appropriate steps for submitting a sample.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement

Functional Areas:
- FDA Inspection Readiness

Partners: FDA

Languages Available:
Spanish (Latin America)
Sarbanes-Oxley Act: An Overview

The Sarbanes-Oxley Act of 2002 initiated the biggest change in corporate governance since the Great Depression. This course describes each section of the Sarbanes-Oxley Act along with insights about how it impacts companies and their employees. Topics in this course include: Purpose, Effects, Audit Committees, Executives, Government Agencies, and Crimes and Penalties. After completing this course, learners will be able to identify the purpose and main provisions of the Sarbanes-Oxley Act.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Ethics & Corporate Responsibility

Functional Areas: Corporate Ethics

Scaffold Safety

This course focuses on preventing fatalities and serious injuries when using scaffolds. Consistent work practices are identified that should be followed at all times. Topics in this course include: Types, Users, Support, and Procedures. After completing this course you will be able to prevent hazards from occurring while using scaffolding.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: Environmental Health and Safety

Functional Areas: Workplace Safety

Scope of Standard and Equipment Classification

Learn how to easily identify the equipment covered under the IEC 60601-1 standard and how to evaluate equipment based on the classifications found in Clause 6.

Format:

Libraries: Engineering Safety

Functional Areas: IEC 60601

Section 1557 of the Affordable Care Act

This course discusses the requirements of Section 1557 of the Affordable Care Act. After completing this course, learners will be able to identify the Section 1557 requirements, who they apply to, and consequences for not meeting the requirements.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: PPACA

Security Measures for Employees

This course offers all employees ways to ensure they are helping to protect against theft, sabotage, or harm to themselves, their fellow employees, and their company.

Format: eLearning - HIP2

Libraries: Ethics & Corporate Responsibility

HR Compliance & Risk Management
Selecting and Managing Clinical Contract Research Organizations (CROs)  
This course provides information on the processes commonly used to select and manage a clinical contract research organization (CRO) and other supportive contract service providers for the clinical stages of the investigation product development process. Topics in this course include: Outsourcing, Pre-Selection Criteria, Selection Techniques, Managing CROs, and Communications. After completing this course, learners will be able to identify the requirements for selecting and effectively managing CROs and other service providers.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Clinical: Medical Device  
- Clinical: Pharmaceutical

Functional Areas:  
- GCP - Clinical Management

Languages Available:  
- French (European)  
- German  
- Spanish (Spain)

Self-Motivation  
This course covers the five characteristics of self-motivated people and the five skills that are necessary to develop these characteristics. Topics in this course include: Self-Motivation, Skills, Mission Statement, Goals, Creative Thinking, Self-Discipline, and Self-Talk. After completing this course, learners will be able to recognize how to apply the skills and characteristics of self-motivation at work, at home, and in the community.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:  
- Ethics & Corporate Responsibility  
- HR Compliance & Risk Management

Functional Areas:  
- Professional Development

Sexual Harassment Awareness for Employees  
Sexual harassment is a serious issue facing employers. This course is designed to educate you about the Equal Employment Opportunity Commission's (EEOC) definition of sexual harassment as well as to present information on identifying harassing behavior, avoiding harassment, and what steps to take should harassment issues arise involving the workplace. Topics in this course include: Definition, Guidelines, Confrontation, and Reporting Incidents. After completing this course, learners will be able to identify behaviors that are considered inappropriate and know how to avoid engaging in inappropriate behaviors.


Libraries:  
- Ethics & Corporate Responsibility  
- HR Compliance & Risk Management

Functional Areas:  
- Harassment Topics

Content Bundles:  
- HR Compliance
Sexual Harassment Awareness for Managers

This course presents an overview of sexual harassment and emphasizes the specific responsibilities of managers and supervisors in preventing and responding to sexual harassment. Responding appropriately to sexual harassment may reduce the potential liability of employers in this area. It is highly recommended that individuals take Investigating Employee Claims in conjunction with this course. Reviewing Sexual Harassment Awareness for Employees will also be helpful. Topics in this course include: Definitions, Employer Liabilities, Prevention and Response, and Legal Issues. After completing this course, learners will be able recognize, prevent, and respond to sexual harassment in a responsible manner.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Ethics & Corporate Responsibility, HR Compliance & Risk Management

Functional Areas: Harassment Topics

Sexual Harassment Awareness for New York Employees and Supervisors

Sexual harassment is a serious issue facing employers. This course is designed to educate you about New York and federal laws regarding sexual harassment as well as to present information on identifying harassing behavior, avoiding harassment, and what steps to take should harassment issues arise involving the workplace. Topics in this course include: Guidelines, Confrontation, Reporting Incidents, Supervisor Responsibilities, and Rights and Remedies. After completing this course, learners will be able to recognize that harassment is a personal issue and that definitions of offensive behavior may differ amongst coworkers. Learners also will be able to identify behaviors that are considered inappropriate and recognize how to avoid engaging in inappropriate behaviors.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: HR Compliance & Risk Management, Ethics & Corporate Responsibility

Functional Areas: HR Compliance

Sexual Harassment Policy

The Sexual Harassment Policy states that this Company is committed to a work environment free from any form of sexual harassment. It defines harassment and outlines employee responsibility as it relates to both the harasser and the harassed.

Format: Policy

Libraries: HR Compliance & Risk Management

Functional Areas: Harassment Topics
SMART Goal Setting

Goals that adhere to Specific, Measurable, Attainable, Results-Oriented, and Time-Bounded (SMART) criteria are more likely to lead to completion of tasks and higher satisfaction. This course will help participants understand the impact of goal setting on their lives, and give them a road map they can use to achieve higher personal and professional productivity. Topics in this course include: Goals, Specific, Measurable, Attainable, Results-Oriented, Time-Bound, and Putting It Together. After completing this course, learners will be able to recognize the essential elements of effective goal setting. Learners will also be able to differentiate between well-written and poorly written goals.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- HR Compliance & Risk Management

Functional Areas:
- Professional Development

SPCC Plans for Non-Production/Bulk Storage Facilities

SPCC Plans for Non-Production/Bulk Storage Facilities discusses SPCC requirements of an onshore non-production oil facility. First, the course gives background and general information about the SPCC Plan. Then, it discusses the general requirements of an SPCC Plan. Lastly, it discusses facility drainage requirements, bulk storage container requirements, and transfer operations requirements.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

SPCC Plans for Onshore Production Facilities

SPCC Plans for Onshore Production Facilities discusses SPCC requirements of an onshore oil production facility. First, the course gives background and general information about the SPCC Plan. Next, it discusses the general requirements of an SPCC Plan. Also, it discusses facility drainage requirements, bulk storage container requirements, and transfer operations requirements. Lastly, it discusses the Plan requirements for drilling and workover facilities.

Format:

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

Special Investigations

This course will provide an overview of the broad spectrum of investigations performed by the Food and Drug Administration (FDA). Topics in this course include: Complaint Investigation, Surveillance Investigation, Disaster Investigation, Health Fraud Investigation, Product Tampering Investigation, and Criminal Investigation. After completing this course, learners will be able to identify the purpose of special investigations. Learners will also be able to recognize the properties of special investigations, as well as things to look for during each of these investigations.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
- FDA Inspections and Enforcement

Functional Areas:
- FDA Inspection Readiness

Partners: FDA
Special Needs Plans: Model of Care

The Model of Care (MOC) is considered a vital quality improvement tool and integral component for ensuring that the unique needs of each beneficiary enrolled in a Special Needs Plan (SNP) are identified and addressed. Topics in this course include: Background, MOC 1: SNP Population, MOC 2: Care Coordination, MOC 3: SNP Provider Network, and MOC 4: Quality Measurement and Performance Improvement. After completing this course, learners will be able to identify the required elements of a Special Needs Plan’s Model of Care as well as the scoring criteria that are used as part of the review and approval process.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Medicare Advantage, Medicare Part D

Sterile Dosage Forms Introduction

Because of the risk of infection from non-oral medications, manufacturers must ensure the sterility of sterile dosage forms. This course describes the reasons that some drugs need to be sterile and the practices required for sterile dosage form manufacturing. Topics in this course include: Sterility, Requirements and Preparations, and Cleanrooms. After completing this course, learners will be able to identify the role of cleanroom facilities and personnel in the sterile dosage forms manufacturing process.

Format: eLearning - EduFlex, eLearning - SCORM
Libraries: Not specified
Libraries: Functional Areas: Aseptic Processing
Programs: Aseptic Processing: Advanced Series

Structure of IEC 60601

Gain an understanding of the nomenclature and structure around the 60601 series and explore the relationships of the general standard to collateral standards, particular standards, amendments and national deviations.

Format: Engineering Safety
Libraries: IEC 60601

Structure-to-Electrolyte Surveys

Structure-to-Electrolyte Surveys explains the equipment needed for a structure-to-electrolyte survey and equipment maintenance, structure-to-electrolyte readings, meter usage, close interval surveys, and logging data. Abnormal operating conditions (AOCs) that may be encountered while performing structure-to-electrolyte surveys are included, along with possible responses.

Format: DOT Operator Qualification - Oil And Gas Pipeline
Libraries: Midstream Topics

Languages Available:
French (European) (Aseptic02)
German (Aseptic02)
Spanish (Spain) (Aseptic02)
Chinese (Simplified) (Aseptic02)
Substance Abuse

Employee substance abuse is one of the most troubling issues facing modern businesses. This course discusses substance abuse as it affects both the workplace and the home. Topics in this course include: Substance Abuse, Alcohol Abuse, Alcoholism and Self-Evaluation, Drug Abuse and Addiction, and Response. After completing this course, learners will be able to recognize psychological and physical effects of substance abuse and the common behavior characteristics of co-workers and family members with abuse problems.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries:  
- Ethics & Corporate Responsibility  
- HR Compliance & Risk Management

Functional Areas:  
- HR Compliance

Content Bundles:  
- HR Compliance

System Control: Control Room Management Regulations

System Control: Control Room Management Regulations is an overview of the control room management provisions of 49 CFR 192 and 49 CFR 195. Major provisions of the CRM amendment are addressed, including written CRM procedures, roles and responsibilities, adequate information, point-to-point verification, fatigue, alarm, and change management, operator experience, training, and compliance validation and deviation.

Format:  
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

System Control: Fatigue Management for Controllers

System Control: Fatigue Management for Controllers examines countermeasures that natural gas hazardous liquids pipeline controllers and other shift workers can take to prevent fatigue. Strategies that these workers can take both at home and at work are discussed.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

System Control: Fatigue Management for Supervisors

System Control: Fatigue Management for Supervisors examines how control room supervisors can recognize and manage fatigue on the part of controllers who work with SCADA systems for natural gas and hazardous liquids pipeline operators. The fatigue mitigation strategies in this course are also useful for supervisors of shift workers at compressor and pump stations and other workers involved in around-the-clock operations such as pigging, hydrotesting and dewatering, pipeline tie-ins, and new pipeline and station construction.

Format:
Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics
Systems Based Drug Inspections

FDA has a series of compliance programs that provide guidance and instructions to help meet FDA regulations for pharmaceutical manufacturers. This course describes FDA’s Drug Manufacturing Inspections program. Topics in this course include: Guidance, Systems, Inspections, Quality, Facilities and Equipment, Materials, Production, and Laboratory Control. After completing this course, learners will be able to recognize what can happen if a firm is not following FDA regulations.

Format: eLearning - EduFlex, eLearning - SCORM

Testing for Bacterial Endotoxins

This course will provide a general overview of bacterial endotoxins and the methods used to test for their presence in products. Topics in this course include: Endotoxin Reduction, Gel-Clot LAL Testing, Chromogenic LAL Testing, and Choosing a Test. After completing this course, learners will be able to recognize the principles of bacterial endotoxins and ways they are detected in products.

Format: eLearning - EduFlex, eLearning - SCORM

The Approval Process for New Medical Devices

This course provides an overall view of the development regulatory process for legally marketing a new medical device in the US. Topics in this course include: Classification, Approval Process, IDE, Clinical Studies, and PMA. After completing this course, learners will be able to identify the major steps in new device development and the required regulatory process for the US market. Learners will also recognize the purpose and requirements of clinical studies. Learners will be able to identify the elements of a 510(k), an IDE, and a PMA. Finally, learners will recognize key information about the classification of medical devices and the role of FDA in the approval of medical devices for the US marketplace.

Format: eLearning - EduFlex, eLearning - SCORM

The Clinical Development Process: Investigational Product, Plan, and Data Management

This course will discuss the clinical development process, including the regulatory obligations of the sponsor of a new drug or product. Topics in this course include: Clinical Research Plan, Protocol Plan, Subject Selection Process, Data Collection, and NDA Submission. After completing this course, learners will be able to identify the steps leading to the final FDA review and approval for marketing of a new product.

Format: eLearning - EduFlex, eLearning - SCORM
The Design and Development of Software Used in Automated Process Controls

Regulators require that manufacturers apply the principles and practices of software quality assurance to automated systems that may ultimately affect product safety and effectiveness. This course examines the process of developing software for automated process control. Topics in this course include: Automated Process Controls, Specifications and Design, Verification and Validation, and Maintenance and Retirement. After completing this course you will be able to identify the Software Development Life Cycle (SDLC) and recognize several aspects of software quality assurance and documentation.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:
- GMPs - Process
- Validation

The Mentoring Process

The Mentoring Process examines mentoring and counseling basics, an effective mentoring system, the need for mentoring and counseling, mentor roles and responsibilities, ethical behavior, needs of adult learners, trust and rapport building, communication techniques, listening skills, giving feedback, and conflict resolution.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:
- DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas:
- Midstream Topics

The Role of the Clinical Research Associate

This course explores the role of the clinical research associate (CRA) in monitoring a clinical trial and acting as a liaison between the investigative site and the sponsor company. The course will introduce key CRA responsibilities widely recognized throughout the industry and globally applicable. Topics in this course include: Definition, Visits, Recruitment and Retention, Informed Consent, Source Documentation, and Essential Documents. After completing this course, learners will be able to recognize the current role of the CRA during each stage of a clinical trial and identify specific responsibilities for documents and processes in those stages.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: Corexcel

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- GCP Basics

The Role of the Clinical Research Coordinator

The clinical research coordinator (CRC) has a key role in executing a clinical trial and acting as a liaison to the investigator, sponsor, and monitor. This course will introduce key CRC responsibilities at the site, including subject recruitment, informed consent, source document and case report form (CRF) completion, and test article accountability. Topics in this course include: CRC, Visits Before Study, Visits During & After Study, Recruitment & Retention, Informed Consent, Source Documentation, Case Report Forms, and Essential Documents. After completing this course, learners will be able to identify the CRC’s key roles in research and patient protection from pre-study visits through study completion.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: Corexcel

Libraries:
- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:
- GCP Basics
Tool Safety

Thousands of workers are injured every year due to improper use of hand and portable power tools. These injuries can be prevented if proper tool use is followed. This course presents the most common tool hazards, safe selection and use of tools, tool inspections and modifications, and the proper storage and maintenance of tools.

Format: eLearning - HIP2
Libraries: Environmental Health and Safety
Functional Areas: EHS Basics

Toxic Substance Control Act (TSCA) Reporting

Approximately 75,000 chemical substances are used in American commerce today. While many substances pose health or environmental risks, some toxic substances pose particularly unreasonable risks, and therefore must be tracked and regulated by the Environmental Protection Agency (EPA). This course presents information about how companies and employees must work together to report information about these chemical substances to the EPA.

Format: eLearning - HIP2
Libraries: Environmental Health and Safety
Functional Areas: Toxic Substance Control

Trade Secrets

In this training, we discuss the importance of safeguarding our company's trade secrets in order to keep our competitive edge in the marketplace.

Format:
Libraries: Ethics & Corporate Responsibility
Functional Areas: Ethics Basics

Tuberculosis: Exposure Prevention and Control

TB kills almost 3 million people a year. It is the leading cause of death from an infectious agent in the world. In recent years, a number of outbreaks of this disease have occurred in hospitals, correctional institutions, homeless shelters, nursing homes, and residential care facilities for AIDS patients. Nationwide, at least several hundred people have become infected, and have required medical treatment after workplace exposure to TB. This course presents the basics of how TB infects and spreads, how to recognize signs and symptoms of TB, and how to protect yourself around known or suspected TB patients.

Format: eLearning - HIP2
Libraries: Environmental Health and Safety
Functional Areas: EHS Basics, Medical Device

U.S. Trade Controls

Your participation in this training will help you follow U.S. law and our Company's policies regarding export and import control, economic sanctions, and antiboycott regulations.

Format:
Libraries: Ethics & Corporate Responsibility
Functional Areas: Ethics Basics
Ultrasonic Thickness Testing

Ultrasonic Thickness Testing examines the purpose and applicability of ultrasonic thickness testing. The steps for conducting an ultrasonic thickness test are explained, as are pipe or metal surface preparation, and use of couplant gel.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Underground Storage of Natural Gas and Liquids

Underground Storage of Natural Gas and Liquids addresses underground storage in the energy industry, similarities and differences of gas and liquids products, basic storage functions and terms, different types of underground storage, and the purpose and function of underground storage equipment.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Understanding GMPs for Facilities and Equipment

Facilities and equipment GMP requirements impact many aspects of plant operation — from setup to maintenance and cleaning. This course introduces the general layout and equipment used within a pharmaceutical or medical device manufacturing plant. Topics in this course include: Facilities, Cleanliness, Process Flow, Equipment, Maintenance, Calibration, and Cleaning. After completing this course, you will recognize the importance of Good Manufacturing Practices and you will be able to identify the requirements that specifically apply to facilities and equipment.

Format: eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

Libraries: Medical Device GMPs, Pharmaceutical GMPs

Functional Areas: Maintenance and Facilities

Content Bundles:
- Medical Device - GMP
- Maintenance and Facilities - Basics

Partners: FDA

Languages Available:
- German (PHDV63)
- French (European) (PHDV63)
- Japanese (PHDV63)
- Spanish (Spain) (PHDV63)

Understanding Post-Approval Changes

FDA has made a number of recent changes to its regulations concerning post-approval manufacturing changes for drug products. This course covers categories of post-approval changes (PAC), the requirements for each, and PAC guidance. Topics in this course include: SUPAC, Components and Composition, Site of Manufacture, Scale of Manufacture, and Manufacturing. After completing this course, learners will be able to recognize the requirements related to PAC and FDA guidance for those requirements.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medical Device GMPs, Pharmaceutical GMPs

Functional Areas: Pharmaceutical GMP Basics
Understanding the Principles and Practices of Process Controls

Recently FDA has become increasingly concerned with the number of Warning Letters being issued due to problems with the control of manufacturing processes. Items listed in these various Warning Letters include lack of validation of manufacturing processes, lack of written procedures, improper sampling and testing of materials, and failure to follow written procedures. This course provides an understanding of what process control is. You will also learn about the written procedures involved in validation, how equipment affects process controls, batch production records, correct sampling and testing methods, proper reprocessing techniques, contamination control, change control, and process analytical technology.

Format: eLearning - Eduflex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Languages Available: Japanese (PHA47)

Uniform Hazardous Waste Manifest Completion

Companies ship millions of tons of hazardous waste every year. The United States Environmental Protection Agency (EPA) and the Department of Transportation (DOT) require industries to track the generation, shipment, and disposal of hazardous wastes through the use of specified forms. The form used for the transportation of waste is the Uniform Hazardous Waste Manifest (UHWM). After completing this course, the participant will know how to complete and correctly distribute the UHWM.

Format: eLearning - HIP2

Up-Rating Pipeline Systems

Up-Rating Pipeline Systems teaches the learner how to determine present system and facilities conditions, review proposed up-rate pressures, understand and write an up-rate plan, determine system conditions prior to pressure increases, and maintain required up-rate records.

Format:

Using a Digital Multimeter

Using a Digital Multimeter begins by introducing learners to the metric system and how to apply it to using a multimeter. The course also explains the basic concepts behind electricity such as resistance, voltage, and amperage. Finally, it discusses how to use a multimeter to measure resistance, voltage, and amperage.

Format:
Using the DTEX® Odorant Detection Instrument

Using the DTEX® Odorant Detection Instrument teaches the learner about the DTEX DX1000G/L odorant detection instrument system and how to conduct an odor concentration test.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Using the Heath Gasurveyor® 3-500

Using the Health Gasurveyor® 3-500 examines the components, range of operation, and key functions of this combustible gas indicator, and also explains how to operate the instrument.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Using the Heath ODORATOR®

Using the Health ODORATOR® explores how this odorant detection instrument works, explains how to operate and troubleshoot the instrument, and provides additional information that will help the user skillfully operate the instrument.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Using the Metrotech Pipe Locator

Using the Metrotech Pipe Locator explains how to use this pipe locating instrument, including the three primary locating methods: direct connection, inductive coupling, and the inductive method. Also examined are instrument checkout procedures, tracing techniques, and maintenance requirements.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics

Using the Radiodetection Pipe Locator

Using the Radiodetection Pipe Locator teaches techniques for locating buried pipeline and cables using the Radiodetection Pipe Locator. The course also explains how to operate the Radiodetection receiver and transmitter. Tips for using the Radiodetection locator are also provided.

Format:
Libraries: DOT Operator Qualification - Oil And Gas Pipeline
Functional Areas: Midstream Topics
Using the T82 Single Gas Monitor

Using the T82 Single Gas Monitor introduces operators to the T82 Single Gas Monitor and teaches how to operate this sensitive instrument. Calibration, maintenance, and smart sensor modes are also addressed.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Validation of Analytical Laboratory Procedures

This course introduces developers and those individuals involved in validation of analytical methods to the regulatory requirements for the validation of analytical laboratory procedures. Topics in this course include: Validation Characteristics, Specificity, Linearity and Range, Accuracy and Precision, Detection/Quantitation, Robustness, and Revalidation. After completing this course, learners will be able to identify applicable regulatory requirements and recognize the important aspects of analytical methods validation, including the data that must be generated.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Global Regulatory

Functional Areas: ICH: Quality Management

Valve Actuators

Valve Actuators explains the various styles and design features of actuators/operators and how they operate. Proper maintenance techniques and reconditioning of hydraulic actuators/operators is discussed in this course. Common abnormal operating conditions (AOCs) that may be encountered while inspecting or maintaining valve actuators/operators are identified, including proper reactions.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics

Vault Inspection and Confined Space Entry

Vault Inspection and Confined Space Entry addresses key regulations about vault maintenance and inspection. Topics include vault inspection; hazardous atmospheres; vault entry; OSHA requirements for permit-required confined space entry; confined space hazards, entry planning, and pre-entry training; and prevention of accidental ignition.

Format:

Libraries: DOT Operator Qualification - Oil And Gas Pipeline

Functional Areas: Midstream Topics
Disputes between employees, or between employees and their supervisors, are not unusual in a stressful workplace environment. Occasionally, conflicts may escalate into heated exchanges or even a physical confrontation. Every year, a handful of cases involve extreme violence, including the use of firearms, and result in severe injuries or the tragic loss of life. After completing this course, participants will know how to identify individuals prone to violent behavior and apply proven techniques to diffuse dangerous situations.

**Walk-Behind Forklifts**

Walk-behind forklifts are used as an efficient and economical way of moving materials. While they have many benefits, these vehicles can be deadly when operated incorrectly. To avoid these injuries, it is important to know how to operate a walk-behind forklift safely and how to avoid dangers in the work area. This course presents information about how and when walk-behind forklifts are used and how to determine whether a walk-behind forklift is safe to operate.

**Walking and Working Surfaces — Affected Person**

This course discusses accident prevention and the general requirements for walking and working surfaces. Topics in this course include: Causes and Prevention. After completing this course, learners will be able to recognize the causes of slips, trips, and falls in the workplace and how to prevent them.

**Welcome to ComplianceWire**

This course will help new users become acquainted with the features of the platform, so that they may optimize their online learning experience. Participants in this course will learn the basic components of the platform learning environment.
Weld Repairs and Welding Procedures

Weld Repairs and Welding Procedures examines the functions of a welding inspector; percentages of each day's butt welds to be tested, depending upon class location; when nondestructive testing is required; common welding defects and how to cure them; information needed on welding inspection reports; and essential variables.

Weld Repairs and Welding Procedures

EY-602WREPR

Welder Qualification

Welder Qualification addresses butt, fillet, and 90-degree branch welds; safety precautions for welders; essential variables; single and multiple qualification tests; macro-section tests and face bend tests on branch and sleeve welds; and typical welder qualification tests.

Welder Qualification

EY-601WQUAL

Welding Safety

Welding, cutting, and brazing are the cause of over 500,000 workplace incidents each year, causing blindness, injuries, and even death. This course discusses welding safety, including personal protective equipment and appropriate procedures for avoiding injury. Topics in this course include: Definition, Hazards, Safety Rules, PPE, Oxy-Fuel Safety, Electric Arc Safety, and Confined Spaces. After completing this course, learners will be able to identify the basic safety procedures around welding, cutting, and brazing.

Welding Safety

EHS106

Work Zone Safety

Work Zone Safety describes the types of signs used in work zone traffic control and explains the specifications for proper warning signs. It also discusses work zone and traffic control safety measures as well as proper flagging procedures.

Work Zone Safety

EY-108WKZONE

Working With the Media During an Emergency

Working with the Media During an Emergency addresses appropriate interview protocols with the news media and emergency response officials at the scene of a pipeline emergency.

Working With the Media During an Emergency

EY-ER1302
Writing and Reviewing SOPs

Manufacturing facilities rely on Standard Operating Procedures (SOPs) to establish controlled manufacturing processes for quality products. This course identifies the principles and practices applicable to written SOPs. Topics in this course include GMP Requirements, Elements of SOPs, Review & Approval, and Document Control. After completing this course, learners will be able to recognize the different types of SOPs and methods for developing them. Learners will also be able to identify the appropriate measures for document control.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM
**Partners:** FDA

**Languages Available:**
- Spanish (Latin America) (PHA48)
- German (PHA48)
- French (European) (PHA48)
- Chinese (Simplified) (PHA48)
- Japanese (PHA48)

Writing Validation Protocols

This course is an introduction to the importance and content of the documentation that comprises validation. Topics in this course include: Validation, Documentation, and Elements. After completing this course, you will be able to identify validation protocols and the three types of qualifications. You will also be able to recognize the key elements involved in writing a validation protocol.

**Format:** eLearning - EduFlex, eLearning - SCORM
**Partners:** FDA

**Languages Available:**
- Chinese (Simplified)
- Japanese
About UL PURE™ Learning

Since 1980, UL PURE™ Learning has been providing computer-based instruction, compliance management solutions, and advisory services to corporate and government customers with a strong focus on the needs of Life Sciences, Health Care, Energy, and Industrial sectors.

Our unique partnership with the FDA provides online training tools to train and certify more than 36,000 federal, state, local and global investigators in the areas of quality and compliance. UL and the FDA jointly develop content and deliver it via ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. More than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.