# Ten Essential Features Every Life Sciences Learning Management System (LMS) Needs Today

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When it comes to regulatory compliance, biologic, medical device and healthcare organizations have ultra-specific feature requirements.

Designed from its inception as a tool to serve the life sciences, UL's ComplianceWire® uniquely addresses these requirements at its foundation.

Other LMS software development teams would struggle to add this level of conformance into their systems, as these features are embedded in the very core of the learning management system.

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Based upon client feedback, we've outlined below how UL's ComplianceWire LMS helps clients to meet these exacting regulatory requirements:

### 1. Assignment-based training functionality

According to 21 CFR 211.25(a), the purpose of training is to develop the knowledge and skill of personnel so they can perform their jobs correctly.

Qualification is the formal process of assessing and documenting the ability of personnel to perform job tasks correctly and consistently in accordance with prescribed requirements.

ComplianceWire enables training managers to define role-based qualification groups, with automated group membership and assignment rules, for corresponding requirements curricula.

Importantly, training completions are time-stamped and unable to be edited in the system, creating an unimpeachable record that meets the standards set forth in 21 CFR Part 11.

### 2. Audit trails on critical assignment activities

21 CFR Part 11 requires the use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.

With ComplianceWire, system administrators can access the system Event Log to view more than 250 events provided by the system, such as "adding an assignment" or "removing a security role from a user."

The administrator can easily build a list of up to five selected events that meet specific criteria such as user ID, last name, first name, etc.

Administrators can also choose to view only today's events or display events for 30 days.

### 3. Flexible security roles

While many learning management systems provide a "security role" functionality, life sciences organizations demand extremely tight security roles, limited to specific individuals who can perform itemized system changes, such as modifying system configuration, updating training items, making assignments, and more.

ComplianceWire enables administrators to strictly "define" specific security roles based on different functions they will need as managers, trainers, IT personnel.

### 4. Electronic signatures on assessments and SOPs

According to 21 CFR Part 11: *Signed electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.*

Also, electronic records need to contain information associated with the signing that clearly indicates the printed name of the signer, the date and time when the signature was executed and the meaning (such as review, approval, responsibility, or authorship) associated with the signature.

ComplianceWire electronic signatures are comprised of the signer information, including the First Name, Last Name, and User ID within the system.

The system's electronic signatures are comprised of the computer-generated date and time stamp when the signature was executed.

In addition, users can enter the meaning/reason associated with the signature. Signature reasons are customizable by each customer to meet specific needs.

### 5. Real-time reports for managers and administrators

A key factor to the success of an LMS is an organization's ability to gauge the effectiveness of their training programs.

The basis for measuring this success is largely achieved through the creation and analysis of training analysis reports. This occurs after training items have been created, assignments have been made and learners have been trained.

Unfortunately, the reporting functionality within an LMS can often make it difficult to appropriately extract training data and understand the effectiveness of the training.

Life science companies require these key components from reports within an LMS:

- Provide details on the orientation training that describes GMP regulations and instructions.
- Demonstrate that work processes have been documented to identify critical skill-based job tasks and operations.
- Demonstrate how employees receive retraining on an SOP (procedures) if critical changes have been made in the procedure, or if in response to a corrective action.
- Indicate how on-going, periodic GMP training is accomplished.
- Show all training assigned and the status of each training item for employees.
- Demonstrate that on-the-job training was performed for each function to be performed (before the employee is allowed to perform such tasks).
- Present training documentation that indicates training dates, training content, and the signature of the employee and the trainer.
- Demonstrate training records are readily retrievable, easily determine what training an employee has received, which employees have been trained on a particular procedure, or have attended a particular training program.

ComplianceWire makes it easy to generate, customize and schedule your training, compliance and administrative reports in support of your qualification-based life sciences training program.

## 6. Record protection

21 CFR Part 11 requires that systems be validated to ensure accuracy, reliability, consistent intended performance and the ability to discern invalid or altered records.

Companies must have the ability to generate accurate and complete copies of records in both human-readable and electronic form suitable for inspection, review and copying by the agency.

The use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify or delete electronic records is essential

ComplianceWire provides more than 250 audit trails, or log events, that capture the time stamp of when the activity occurred. Life sciences companies should expect log events for many critical activities for audit purposes.

## 7. Role-based assignment functionality

If the LMS does not focus on role-based assignments, management will be unable to review individual training plans against employee job descriptions to confirm accuracy when hired and updated when a change in role takes place.

The margin for human error increases proportionally to the incidence of manual labor required to overcome the lack of automated processes, while additional staff will need to be deployed to support a manual review of the training program.

In contrast to other learning management systems, ComplianceWire was designed to support the creation of role-based groups and assignments to these groups. This dramatically reduces reliance on manual administrative reviews to identify who has the qualification for a specific job role.

Role-based functionality also leads to more successful audit answers when job qualifications are raised. And managers also gain visibility into qualifications for resource planning purposes.

## 8. Secure integrations with essential enterprise systems

### DMS

A life science LMS must provide full version control for all types of training items, most especially controlled documents such as standard operating procedures, policies and work instructions. When GxP controlled documents are revised in the document management system (DMS), the LMS must be capable of automatically triggering new retraining activities for associated role-based qualification groups.

ComplianceWire supports this level of integration with document management systems. When the DMS "versions up" a policy or SOP, ComplianceWire initiates a new training assignment automatically.

### HRMS

ComplianceWire integrates with human resource management systems (HRMS) to automatically create and maintain employee LMS user profiles. Employee data changes in the customer's HRMS are automatically synchronized with the LMS through this integration.

### MES

Manufacturing execution systems (MES) control employees' ability to access designated areas or operate machinery based upon their qualifications. ComplianceWire MES integrations provide employee qualification status data to ensure critical functions are only executed by employees whose qualifications are up to date.

### SSO

Ease of access to the LMS is a critical factor in ensuring effective training results. ComplianceWire readily integrates with customers' identity management and single sign-on (SSO) providers, facilitating easy access to the system while also ensuring electronic signatures meet the requirements under 21 CFR part 11.

### 9. Version control of training items

Not all LMSs provide version control; this gap can make it difficult for QA to successfully "up version" an SOP and automatically trigger new training assignments.

While this factor may not be a major requirement outside of FDA-regulated industry, it does represent an essential requirement for life sciences companies to maintain data integrity.

ComplianceWire supports proper SOP management and the versioning and retention rules that accompany each SOP.

This means "wrapping" a training assignment around the electronic version of the document and then linking to that specific document version on the network or within the document management system.

### 10. Visibility into training status

Many LMSs provide training status reports. However, these are often individual training status reports, not reports based on qualifications, as mandated by the FDA.

Because of ComplianceWire's role-based approach and support for flexible security roles, as illustrated below, the system provides a manager with targeted visibility into a specific user's training status as it relates to qualification.

The data structure and functionality of ComplianceWire automates required qualification for all employees engaged in GxP initiatives.

This ensures the generation of consistent training programs across all job titles within a specific product area, for example.

And it helps to ensure that companies meet FDA requirements that employees have met qualification before performing operations or accessing systems.

## Today's modern LMS is more than just learning management

A true enterprise learning architecture should support the goals for the management of all learning activities across all areas of the company.

The continuum of regulatory pressures facing life sciences companies are monumental;

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***Implementing a learning program that is not aligned with a QMS can have catastrophic consequences, jeopardizing production output, weakening brand reputation and stagnating long-term growth.***

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We urge established and small and medium-sized life sciences enterprises to place a high priority on the needs of the QA team by building an architecture that enables other areas of the company to recognize their needs, without sacrificing quality and compliance.

## Access the same LMS used by the FDA to train more than 36,000 investigators

UL's ComplianceWire LMS provides pharmaceutical, medical device, healthcare and biologics companies with a cost-effective, scalable solution to rapidly deploy LMS requirements and help critical regulatory submissions stay on schedule.

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