10 "Must-Haves" for the Life Sciences Learning Management System

Why the Life Sciences LMS Needs to Demonstrate Record Control

UL talks to many Life Sciences companies that are exploring learning and development systems that meet the needs of Human Resources, Leadership Development, Sales and Marketing, Product Development, Manufacturing and Quality Assurance (QA).

The challenge for companies is ensuring that the system supports the education and qualification of GxP personnel. In this paper, we explore the detailed needs that Life Sciences organizations have shared with UL, and how UL's ComplianceWire learning management system was built to address these stringent requirements.

To understand exactly what is expected of an LMS that is designed for the Life Sciences industry, we interviewed our own clients and also reviewed recent LMS Request for Proposals from dozens of Life Science companies. We learned that many Life Sciences companies have required the same 10 "must-have" features to reduce risks from regulatory audits, but also to meet their own quality and performance objectives. Here are the 10 "must-haves" in alphabetical order:

1. **Assignment-Based Training Functionality**
2. **Audit Trails on Critical Assignment Activities**
3. **Electronic Signatures on Assessments**
4. **Flexible Security Roles**
5. **Real-Time Electronic Signatures**
6. **Record Protection**
7. **Role-Based Assignment Functionality**
8. **Secure Integration with DMS, including Revision Control**
9. **Version Control of Training Items**
10. **Visibility into Training Status**

ComplianceWire was designed from the start to address these requirements. We believe that LMS software development teams would struggle to include this functionality into a learning management system, as these are "embedded" features that impact many aspects of the application.

In this paper, we discuss how ComplianceWire meets these 10 requirements so that companies can use them when evaluating other learning management systems.

Data Integrity and the Risks of Non-Compliance with FDA

According to the FDA, validation is the formalized documented process for testing computer software and systems, required by a specific Code of Federal Regulations (21 CFR 11.10.a). Failure to validate systems can lead to an FDA 483 Observation or even a Warning Letter. To be compliant, Life Sciences companies must validate all of their software, databases, spreadsheets and computer systems and develop the appropriate documentation for all phases of the Software Development Life Cycle (SDLC).

QA is responsible for meeting global regulatory requirements and assuring that individuals have been trained and are qualified for their job functions. In the United States, the FDA has defined stringent regulations around trained and qualified personnel. Likewise, in the European Union (EU), companies must demonstrate that both personnel and "qualified personnel" – those responsible for conducting the training – have been adequately trained. In addition, both US- and EU-based Life Sciences companies must meet stringent computerized system requirements, such as validation, electronic copies, audit trails, record retention and more, as mandated by 21 CFR Part 11 and EU Annex 11.

The QA team needs an LMS that can ensure – and enforce – standardization, organization and reporting of specific and meaningful role-based "qualification" requirements. According to regulations, employees must be able to demonstrate documented qualification that they can perform their specific job functions. "Qualification" could be represented by a collection of "role-based" training items or tasks that must be completed to satisfy the defined expectations of the training manager or department manager.

21 CFR Part 11 is made up of two major subparts that provide guidelines that regulated companies must minimally follow to achieve the level of integrity, reliability, and consistency of electronic records and signatures acceptable to the FDA.

Complying with the Part 11 regulation requires a combination of strong management procedures and computer systems that meet the technical aspect of the guideline such as application security, audit trails, and password protection.

10 Critical "Must Haves" of the Life Sciences Learning Management System:

Assignment-Based Training Functionality

Audit Trails on Critical Assignment Activities

Electronic Signatures on Assessments

Flexible Security Roles

Real-Time Electronic Signatures

Record Protection

Role-Based Assignment Functionality

Secure Integration with DMS, including Revision Control

Version Control of Training Items

Visibility into Training Status

10 "Must-Haves" for the Life Sciences LMS

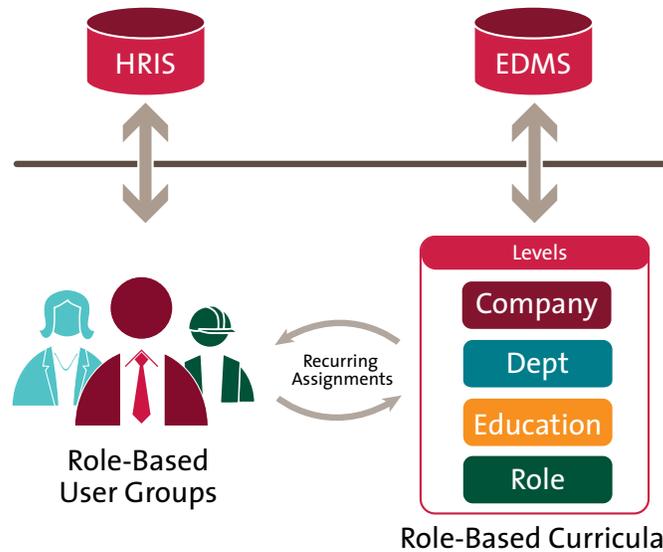| LMS "Must-Haves:" (listed alphabetically)	How ComplianceWire Addresses this Requirement:
1. Assignment-Based Training Functionality	According to 21 CFR 211.25(a), the purpose of training is to develop the knowledge and skill of personnel so they can perform their jobs correctly. Qualification is the formal process of assessing and documenting the ability of personnel to perform job tasks correctly and consistently in accordance with prescribed requirements. ComplianceWire enables managers and trainers to define role-based qualification groups and then assign a role-based curriculum to this group. Importantly, the training is "required" with specific "due dates." Importantly, when the user completes the training, the date of the completion is time-stamped and unable to be edited in the system.
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, only system administrators can access the "Event Log" from the Logs area of the system to view more than 250 events that are 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 a 30-day period.
3. Electronic Signatures on Assessments	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.
4. Flexible Security Roles	While many LMSs provide "security role" functionality, Life Sciences organizations demand extremely tight security roles so that only specific individuals can make itemized system changes, such as modifying system configuration, updating training items, making assignments, and much more. ComplianceWire enables administrators to strictly "define" specific security roles based on different functions they will need as managers, trainers, IT personnel.

10 "Must-Haves" for the Life Sciences LMS (continued)

LMS "Must-Haves:" *(listed alphabetically)*	How ComplianceWire addresses this Requirement:
5. Real-Time Electronic Signatures	When class assignments are completed, for example, ComplianceWire forces learners to enter their electronic signature and then "time stamps" the actual date the class activity was completed. For data integrity purposes, this is a critical feature for regulation agencies.
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. 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. 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 LMSs, ComplianceWire was designed to support the creation of role-based groups and assignments to these groups. This greatly reduces the reliance on manual, administrative reviews to determine who is qualified for a specific job function. 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 Integration with DMS, including Revision History	As noted in a later "must-have" item, the LMS must provide full version control for all types of training items. That is, LMS logic must trigger a new training activity when a GxP document is changed from Version 1 to Version 2, for role-based qualification purposes. 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. In addition, the system integrates with HR systems, Manufacturing Execution Systems and others. In addition, the UL team has experience with active directory authentication via secure LDAP and SAML. The LMS should require an ID, Password and company code to authenticate a user. The LMS also should contain interoperabilities that enable end users to access the system using existing company sign-in methods, including biometrics.

10 "Must-Haves" for the Life Sciences LMS (continued)

LMS "Must-Haves:" (listed alphabetically)	How ComplianceWire Addresses this Requirement:
9. Version Control of Training Items	Not all LMSs provide version control, and this gap can make it difficult for QA to successfully "up version" an SOP so that it automatically triggers a new training assignment; this may not be a major requirement outside of FDA-regulated industry, but a core requirement to maintain data integrity. The LMS must support SOP management and the versioning and retraining 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 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 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 ensures that companies meet FDA requirements that employees have met qualification before performing operations or accessing systems.

HRIS

EDMS

Levels

Company

Dept

Education

Role

Recurring Assignments

Role-Based User Groups

Role-Based Curricula

Summary

In a Life Sciences organization, a true enterprise learning architecture should support goals for the management of all learning activities, across all areas of the company. However, the regulatory pressures facing Life Sciences companies are monumental and implementing a learning program that is not aligned with the quality management system can threaten production output, brand reputation and long-term growth.

That's why leading Life Sciences companies evaluating corporate learning systems place a high priority on the needs of the QA team, building an architecture that enables other areas of the company to recognize their needs without sacrificing their commitment to quality and compliance.

About UL Compliance to Performance

UL Compliance to Performance provides knowledge and expertise that empowers Life Sciences organizations globally to accelerate growth and move from compliance to performance. Our solutions help companies enter new markets, manage compliance, optimize quality and elevate performance by supporting processes at every stage of a company's evolution. UL provides a powerful combination of advisory solutions with a strong modular SaaS backbone that features ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. It's more than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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