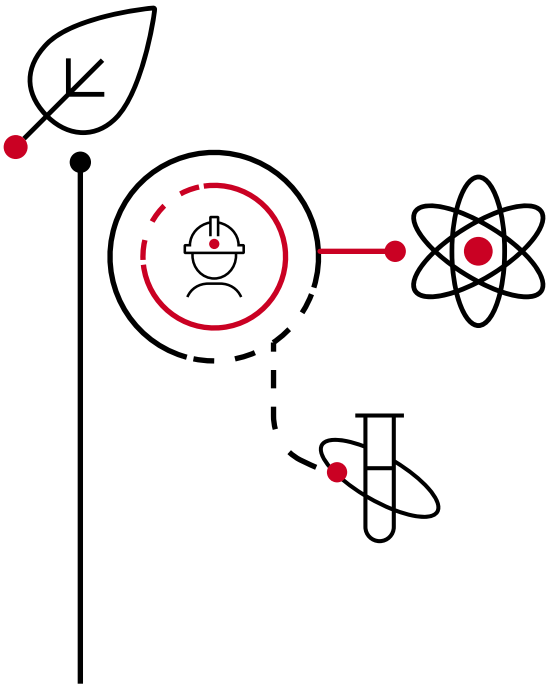

Ten Essential Attributes of a Life Sciences LMS

UL Solutions

Safety. Science. Transformation.™

Ten Essential Attributes of a Life Sciences LMS

Based upon our experiences with customers who have implemented other LMS platforms before engaging with UL Solutions, here are the 10 attributes of an LMS that a Life Sciences company should seek.

1. Does the LMS provide validation support?

The SaaS solution provider should conduct IQ/OQ validation on each major release and provide certification of successful completion. The LMS provider should also provide tools necessary for subscriber to complete their own PQ validation. Specifically, release documentation, testing environment and sample validation scripts.

2. Does the LMS support assignment-based training?

Qualification is the formal process of assessing and documenting the ability of personnel to perform job tasks correctly and consistently in accordance with prescribed 21 CFR Part 11 requirements. In contrast to general industry LMS systems, Life Sciences LMS systems must be designed to support the creation of role-based groups and assignments to these groups. 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. 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.

3. Does the LMS deliver 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. Only system administrators should be able to access the Event Log in the system to view more than 250 events, such as adding an assignment or removing a security role from a user. The administrator should easily be able to build a list of selected events that meet specific criteria such as user id, last name, first name, etc. Administrators should also be able to choose to view only today's events or display events for a 30-day period.

4. Does the LMS securely record and store electronic signatures on completions and assessments?

According to 21 CFR Part 11, signed electronic signatures and handwritten signatures executed to electronic records must 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. Signatures should be comprised of the signer information (including the first name, last name and user ID within the system), and the computer generated date and time stamp. Additionally, LMS systems should support customer customizable meanings/reasons associated with signatures.

5. Does the LMS security support multiple roles for individual users without compromising rigor?

While many LMS's 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. Administrators need to strictly define specific security roles based on different functions they will need as managers, trainers and IT personnel. However, the security role(s) should be flexible enough to allow adoption of multiple roles assigned to single user to perform multiple tasks.

6. Does it perform FDA-compliant record protection?

21 CFR Part 11 requires that systems have the ability to discern invalid or altered records. Your LMS system must be able to produce 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. 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. Systems should provide numerous audit trails or log events, that capture the time stamp of when activities occurred.

7. Does your LMS support version control of training items?

Your LMS must provide full version control for all types of training items. That is, the 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. Not all LMS systems 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.

8. Does it integrate securely and seamlessly with DMS, HR, Manufacturing, ERP and other systems?

When pertinent information is changed in your third party HRIS, manufacturing or ERP system are there linkages in place to update the corresponding records in your LMS? Your LMS should support this level of integration third-party systems. Further to item #7 above, when an SOP is up-versioned in your DMS, your LMS should be able to automatically respond. Also, the LMS also should be able to leverage your company's network authentication to enable end users to access the system using existing company sign-in methods, including biometrics.

9. Does it offer the kind of visibility into training and qualification status required by the FDA?

Many LMS system provide training status reports. However, these are often individual training status reports, not reports based on qualifications as mandated by FDA. Life Sciences focus LMS will have 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 system should automate 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.

10. Authoring tools and content delivery network

WDoes your LMS allow you the ability to easily—and without vendor involvement—tune existing courses to your own company-specific policies and processes? Better yet, does it allow you to easily develop your own custom content?

UL.com/Solutions

PLC23CS753120