Best Practices for Deploying a Learning Management System
As many of today’s regulated companies continue to expand globally and focus on outsourcing of traditional manufacturing and clinical operations, they may struggle with learning management within their quality management and compliance programs. And, as companies seek to transition from a paper-based training process to an online system, they spend a great deal of time evaluating the software vendor’s functionality.

After selecting the system, they often realize that the software alone may not solve their compliance challenges. A system functions best when it is surrounded by well-defined quality plans, processes and procedures that govern the use of the system. This makes the entire learning process sustainable over time.

UL EduNeering has compiled our Learning Management System (LMS) deployment best practices, and have mapped out five deployment stages that will assure compliance and improve the learning experience.

These five stages are based on deployments conducted with more than 250 regulated companies, in which we have helped strengthen their global quality programs via effective training management. Our customers have told us that the deployments and use of ComplianceWire® LMS has: 1) reduced the risks of noncompliance, 2) helped the company realize operational efficiencies, and 3) built a stronger learning culture within their organizations.
Stage#1: Map the Transition from Paper to Platform

Meeting global regulations today means having training records organized and reflective of a well-designed process. And inspectors don’t seem to be particularly biased when it comes to the size of the company. Here’s an excerpt from a Warning Letter delivered to a Medical Device company:

“Failure to establish procedures for identifying training needs, ensuring that all personnel are trained to adequately perform their assigned responsibilities, and that all training shall be documented as required by 21 CFR 820.25(b).

For example, your firm has no training procedures and does not document employee training or qualification. Your firm had two significant changes in management personnel, and a new manufacturing employee was hired yet no training was documented for any of the three new employees.”

Many continue to rely on spreadsheets to manage training records. One company’s story underscores the issues with a paper-based system. This company provided three-ring binders to each employee so they could store their training certifications. During an internal audit, quality assurance personnel had to spend hours preparing audit reports manually, based on classroom training that was conducted on a weekly basis. Just as troubling were the results of the training. For every new version of a SOP, a classroom session was conducted in which employees were expected to “read and understand” these SOP updates, even if the SOP had nothing to do with their job function.

What’s more, the classes provided no test or other measurement activity in which the learners could demonstrate that they “understood” the SOP and any changes that were made. The “check” beside the employee’s name on the sign-in sheet was the only record of interaction. The quality assurance director realized that the paper-based training process was time consuming, costly to administer, and worst of all, not effective. Moving to an electronic system became a clear objective.

What You Need to Consider:

Before a company moves from a paper-based system to a technology platform, quality executives within that company have to map out a more extensive program that leverages the technology, such as:

• Combine various training types to accommodate learning methods (SOP “read and understand,” classroom events, computer-based training, etc.)
• Leverage SOP quizzes, stand-alone product exams and assessment tools that measure competencies, training effectiveness and learner satisfaction
• Provide each learner with visibility into their progress on all activities, from SOP reviews, to classroom activities, to computer-based training
• Factor in the cost savings of a blended learning approach (reduction in travel costs, time away from office, time spent preparing audit reports) as compared to off-site learning
Stage #2: Define a Training Content Ownership Process

Once the “paper-to-platform” transition is defined, the company must define a process that aligns training content to the proper business owners. In most cases, the business owner must ensure that policies and related training are current, consistent and targeted to the right employees or contractors.

What’s more, as content is added, modified or retired, the business owner must approve these changes. It’s critical that content owners follow the coding structure of all learning items consistently over time, utilizing a combination of tools such as how you name your training items and how you group users by training needs. Global companies may demand that the business owner be responsible for translating that content for each global site.

What You Need to Consider:

- Define a procedure for content owners: how often must they review content, how they can add new procedures, how to leverage nomenclature, how to build assessments, etc.
- Content owners must define the appropriate criteria or user attributes that apply to the curricula that they manage
- For each curricula developed, business owners must also consider retraining requirements
- Leverage instructional design techniques to craft quizzes based on critical SOP content

A Quality and Compliance Training Road Map FOR EMERGING FDA-REGULATED COMPANIES

01 Move from Paper to Electronic Platform
02 Standardize Training Content
03 Improve SOP Retention
04 Align the Training Matrix by Role
05 Provide Management Visibility into Training
Stage #3: Develop Processes Based on Platform Functionality

After content owners have been established and a procedure crafted, the next stage relates to training delivery mechanisms. With a paper-based process, the organization’s goal is to have each employee demonstrate documented qualification to perform a specific job function.

The functionality of the LMS will often drive the quality team to re-think – and improve – their existing training processes. Here are two processes that can be shaped by LMS functionality.

Qualification Requirements Process

How an organization defines “qualification requirements” and how the LMS executes on this process may be two different things. The LMS should serve as a repository for storing standardized qualifications and related curricula. Inside each curricula are the training materials or tasks that define the qualification or certification requirements for that role.

User Data Maintenance Process

It’s critical that the quality and compliance leaders identify which attributes of the learner should be captured to deliver the proper training. In the LMS, these attributes will be valuable for building role-based users groups that will receive qualification training. Often, it’s a challenge to understand which user data attributes are meaningful to drive the right training. Companies typically use attributes such as Title, Hire Date, Business Unit, Preferred Language, Department Name/Code, Supervisor/Manager, etc.

What You Need to Consider:

• Develop qualification standards that result in consistent and meaningful reporting metrics for managers and auditors. To ensure that each individual receives the right training, leverage the LMS functionality as much as possible
• While not necessary at launch, consider integrating the LMS with your Human Resource Information Systems (HRIS). In this way, a regularly scheduled feed (say, weekly or daily) from the HRIS to the LMS will update user values that trigger automation of training management, reducing administrative effort
• Your user data management policy should ensure that any changes to end user data are captured in the LMS. Your internal process should account for how user data will be maintained going forward, in light of new hires, departmental changes, contractors and minimizing manual changes to user data
• Define user security roles that are extremely flexible, so they can help define department administrators that can add users, and content owners who can modify or add curricula
Stage #4: Build a Role-Based Training Matrix

At this point you have standardized your qualifications and your nomenclature, and now you need a training matrix, which is simply an inventory of the curricula that will be delivered to specific roles. The training matrix should also include the level at which the training content should be delivered, so content from one business owner (such as a site’s HR team) can be segregated from another business owner (such as the Operations Manager within that site).

The curricula can include training items such as classroom events, on-the-job observation, podcasts, online courses, synchronous training, job-aids, simulations and more. This content shapes the company-defined qualification or certification for each role. Content owners should also be included in this training matrix.

What You Need to Consider:

- Review your existing training matrix and alter your internal processes to align with LMS functionality (how the system automates group membership based on criteria, for example)
- Make sure a curricula’s assignments are of a manageable size for the individual learner; due dates, retraining periods, and sequencing should be automated within the LMS
- The LMS should enable you to organize your user groups by a specific hierarchy type (Facilities, Departments, Roles) to further automate your training matrix management and the way you make assignments
Stage #5: Provide Management Visibility into Training

Finally, your training program should stress accountability, and this means delivering training and performance reports to senior managers and department heads.

For example, a company may define a process in which managers must review incomplete training assignments of their team members. Two other metrics that are used by organizations to measure enterprise-wide effectiveness are: 1) the training completion rate (overall percentage of user completions); and 2) the qualification completion rate (how far along are employees to completing a curricula).
About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.