10 STEPS: BUILDING STRUCTURE INTO YOUR QUALITY TRAINING PROCESS

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"The first rule of any technology used in a business is that automation applied to an efficient operation will magnify the efficiency. The second is that automation applied to an inefficient operation will magnify the inefficiency."

– Bill Gates

When an organization invests in a Learning Management System (LMS), they focus on the functionality and the administration efforts. However, the well-worn IT cliché of "garbage in, garbage out" certainly rings true for any QA team that has rolled out a new LMS.

Without a well-structured training program, the LMS administration effort negates the system benefits:

- Lack of uniformity prevents managers from insight into qualifications;
- Audit managers cannot respond to training-related questions with accurate answers;
- QA executives cannot demonstrate "control" over the training content, as SOP training is out-of-date and procedures have not been reviewed in years.

Without any training structure, the LMS will not deliver the benefits of automation.

Many of the QA teams we talk to are demanding more than just a learning system. They also need to incorporate best practices of other QA teams to improve their governance policies. That was the focus of the UL Webinar held in April: *Adding Structure to a Quality Training Program*. Guest speaker Dave Peterson, Director of GMP and Quality Systems for UL, and part of our Advisory Services team, walked the attendees through 10 time-tested steps that other companies have leveraged to add structure to a program, regardless of what LMS was being used.

Dave recommended that QA teams leverage the ADDIE (Analysis, Design, Development, Implementation, Evaluation) model from the instructional design world, so QA teams could categorize these training structure steps:

Analysis:

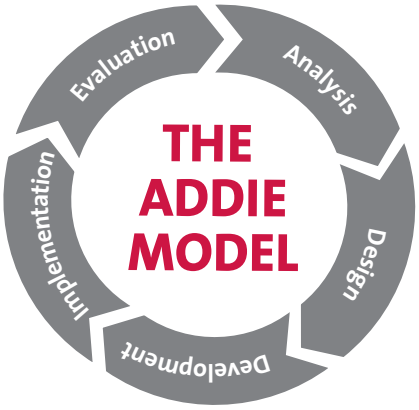
STEP 1 **Define your general strategy and objectives for the assessment** (use an independent third party). This includes a review of your current training policies and SOPs, as well as a review of QA and manufacturing organizational charts, business areas, job descriptions and training plans.

STEP 2 **Conduct a thorough audit of your existing program** to identify gaps and inefficiencies.

Design:

STEP 3 **Establish a "Governance" Board of stakeholders,** which builds organization ownership and encourages collaboration and visibility into the program. The key, Dave said, is to align 'business owners' with the right learning content. This may be business unit managers, engineers and others who will make sure that the content remains relevant and up-to-date.

STEP 4 **Set up a training matrix, which identifies the general organization structure,** including all departments within its scope. The matrix development starts with department manager interviews to identify principal functionality and how tasks are divided into roles, which may span corporate, facility and job function levels.



Development:

STEP 5 **Build "role-based" curricula** for the roles defined in the last step. The business owners must define a "Qualification" for each critical job role, and then identify which learning items should be included in the curriculum. The qualification should reflect regulatory expectations as well as management expectations for knowledge and skills. Dave noted that curricula should include as many training "types" as needed: CBTs, SOPs, internal documents, policies, job aids, external courses, etc.

STEP 6 **Define a uniform coding structure** that spans all departments and locations. All trainers and administrators should employ this coding structure. For example, an SOP on Design Controls for the Princeton, NJ facility could receive this code: US-NJ-GMP-Design-001

Dave also noted that training items should be classified by file format (PDF, PPT, CBT, ILC) in the training matrix to improve reporting filtering and accuracy.

STEP 7 **Define your company's documentation process.** This includes understanding how training training completion records, such as job qualifications and SOPs, etc. will be designed, completed, filed, tracked and easily retrieved. Many of these processes could be defined by the LMS you choose, but it's best to understand "what" records are being captured before you define "how" they will be captured.

Implementation:

STEP 8 **Measure learning effectiveness.** This could be as easy as assigning quizzes and assessments to "high-risk" SOPs and policies to measure retention. But Dave also recommended that QA teams add learning objectives to all learning items. And for operator training, Dave noted a best practice of defining "competencies" with measurable outcomes (e.g. demonstrated performance by the learner before being able to operate equipment).

Dave also suggested that the QA team establish a "train the trainer" program, and define a procedure around "on-the-job" proficiency testing, including remediation should the learner fail the test. Finally, Dave advised the audience to have supervisors, management and the QA team regularly review and evaluate proficiency test results to identify specific problems and trends.

STEP 9 **Provide visibility to managers.** This can be done in a few ways, based on data that's collected. You can provide "compliance status" or "qualification status" metrics reports to departmental managers and supervisors, and also provide regular learning item change notices to managers.

You can also define a regular schedule for changes to policies, SOPs and work instructions, and use consistent revision codes when assigning this training. Dave also noted that you should keep senior management informed with easy-to-read status charts so they are aware of the state of quality compliance.

Evaluation:

STEP 10 **Instill continuous learning.** Dave recommended that QA teams develop refresher training programs based on factors such as deviations from processes (audit staff), process and equipment changes, cross-training as backups and other criteria. The key is to engage employees through continuous learning programs such as new FDA requirements, global regulatory changes, Warning Letter trends, etc.

Summary

By incorporating these steps, and providing multiple training "touch points" throughout the year, companies can reinforce principles and concepts that truly help shape the behavior of employees, while building a culture of quality throughout the organization.

In closing, Dave recommended that QA teams establish ongoing proficiency exams to refocus existing educational programs on knowledge or skill gaps.

About UL EduNeering

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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.

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