Making Training More Precise through Task-Based Competency Assessments
Quality and training managers within many FDA-regulated companies have sought to define training effectiveness by answering two critical questions:

“How can we best ensure that personnel have the necessary education, experience and training to perform their job function?”

“How can personnel demonstrate competency for assigned functions?”

Organizations have long relied on learning management systems to capture training results to reduce the overall administrative effort associated with paper filing and improving record accuracy.

Likewise, the competency assessment (CA) also needs to be captured in the same way that an online course or classroom event is captured as part of an employee’s documented training history. However, the task-based CA can be labor-intensive, in that it’s typically accomplished by a single qualified person observing specific tasks performed by each employee, based on that employee’s sub-speciality within a particular job function. For this reason, quality managers are seeking to automate task-based CAs to streamline the effort, standardize the process, and ensure more accurate training records.

Using examples from the ComplianceWire®, our Learning Management System (LMS) and our SmartForms tool, this paper explores how an automated competency assessment can be embedded into the training workflow, so that followup actions, such as the assignment of additional training or initiating a remedial mentoring program, happen automatically. The result is more precise training and more accurate audit-ready records.
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Task-Based Competency Assessments Within the Training Program

It’s one of the most agonizing findings for a quality manager or training manager to read following an audit:

“The employee’s training history records did not contain the documentation of training or competency assessment related to functions he performed.”

Despite efforts to establish requirements for adequate role-based training and competency evaluation of all employees and contractors, it can be extremely difficult to identify, evaluate and track “individualized” task-based competency assessments within a manufacturing environment. One reason for this is that tasks are often segmented among employees with similar titles, and they may change several times a year.

An Example of the Task-Based CA Challenge

Here’s an example we will use throughout this paper: a “line operator” has become a specialist in several “sub-areas” of the general line operator role. Only the department manager or supervisor is aware of this specialization, and the training and documentation records aren’t able to “drill down” into these specialty areas. And while a task-based CA has been performed through one-on-one mentoring, the event has not been fully documented within the SOPs associated with the role of “line operator.”

To add another layer of complexity, the CA often triggers followup activities. The challenge for the quality team is not the development of a standardized CA – the challenge is how to standardize and document the followup actions, including training. After a mentoring activity occurs, the supervisor or manager may prescribe a corrective and preventive action such as additional training, or simply having the employee review work instructions, or watch other employees perform the action, etc.

The point is that these follow-up actions must be documented as part of the learner’s training record, or else the product quality suffers, and the risk of failing an audit increases.

How the Learning Management System Can Help

In the example above, the organization’s learning management system (LMS), which tracks all training records, can solve the problem with the right tools. An LMS must not only capture the task-based CA completion record, but also provide workflow capabilities that standardize appropriate followup actions related to the task-based CA, thus documenting the entire task-based CA process.
How Online Competency Assessments Add Precision

Before the LMS can properly capture the task-based CA process, an organization needs to define the process. Our clients have captured this process through Competency Assessment SOPs that introduce the concept with language such as this:

“The competency of employees and contractors are to be evaluated semiannually during the first year of employment or contract, and annually thereafter. If the process or work instructions change, the designated trainer must reevaluate the learner’s performance based on these changes. This reevaluation must be conducted by observing employees and contractors for conformance with procedures.”

The process then must include the steps that the qualified trainer must take to record the employee’s performance, and document any followup actions that the qualified trainer must take following the assessment, such as being retrained on “task-based” curricula that is made up of the proper SOPs and other work instructions.

Transforming the CA from Paper to Electronic Format

ComplianceWire has a tool called Forms that enables clients to convert their paper-based competency forms into online forms. This provides a number of benefits:

- Eliminates the need for the paper trail and paper archives, as the competency is captured in electronic format and saved with the learner’s historical record.
- Improves audit reporting, as the electronic record serves as the central repository of all training activities.
- Provides visibility into who has been trained on a particular task, for more efficient resource planning and gap analysis.

This last benefit may provide extra value for the managers who have dozens of operators on their teams. When the online CA is standardized, competency assessments can help supervisors and training managers quickly spot gaps in existing task-based functions versus the training delivered to these teams.

In a paper-based process, the analysis may not reveal patterns that could potentially expose risks to the entire training program. However, online applications such as UL’s Forms tool enable managers to drill down into specific responses that show that the training content is outdated, or missing key equipment or process functions, for example.
Types of Task-Based Competency Assessments

Because UL has more than 200 Life Science clients, we have observed various training programs in which competency assessments have played an important role.

Our ComplianceWire® LMS is designed to meet the stringent needs related to 21 CFR Part 11, and also supports role-based training programs. In ComplianceWire, a learner with the title of “Line Operator” can be automatically placed into a group assigned training for that role.

In addition, our Forms tool enables assessments to be part of these role-based training programs. A unique benefit of Forms is that an assessment can be assigned to the learner and the mentor/trainer/manager, so both are involved in the competency evaluation record that is saved in the learner’s training record.

The task-based CAs shown here represent the most frequently used versions currently being captured in our ComplianceWire LMS.

Trainer Only: Achieve Qualified or Certified Trainer Status

This version enables trainers/mentors/managers to demonstrate their qualifications to manage the task-based CAs among employees. Both the FDA and EMA have stressed in their guidelines that GMP training should only be conducted by approved and qualified individuals.

To fulfill this compliance requirement, this CA version documents the fact that the individual has received the necessary training for the subject on which he or she will be training, and is qualified to be a trainer or mentor.

Trainer Only: Identify and Approve a Checklist of Task Instructions

This version is used to approve training materials (“I certify that the following content is appropriate for this task.”). This version often triggers the training manager and content owner to add new developmental and/or training opportunities which will increase the competency level of individuals assigned to this role.

Learner & Trainer: Capture Direct Observation of Tasks Being Performed

This version is used when a qualified trainer/mentor is observing an employee perform a specific job function. This form or checklist can be entered directly online by the trainer/mentor during or after he or she observes the task being performed. UL’s Forms tool enables both the trainer and learner to electronically sign the training completion before the activity is considered complete.

Learner & Trainer: Identify Tasks that Require Additional Training

This version is completed by both trainers and learners to identify activities performed by each learner that are not being captured in the role-based curricula being delivered to the team.

For example, the job title of “line operator” may involve additional work instructions that are not performed by each employee with that title. The manager or trainer may want to build training curricula for these tasks, then assign them to only the “line operators” who perform them. Through the task-based CA, the manager can identify these individuals and automatically send the targeted training to that sub-group.

Check the tasks that you perform:
- Gather raw materials for batch using RF system
- Weigh off raw materials
- Pour batches into containers
- Transfer drummed material into blenders
- Clean and disinfect work areas
- Document all batch sheet data and cleaning logs
- Stage finished products to shipping or transfer point
When the online CA is standardized, competency assessments can help supervisors and training managers identify gaps between current task-based functions and the training content being delivered.

Automating CA Follow-Up Activities

In order for an LMS to complete the entire task-based CA process, a training record needs to be stored that indicates any followup related to the CA.

For example, the qualified trainer has observed that a particular line operator has performed several tasks incorrectly. This warrants additional training, such as an SOP review or the scheduling of classroom events. To have the entire CA process documented within the LMS, a learner’s failure to meet the intent of a defined standard must automatically trigger the assignment of remedial training.

That’s the premise of ComplianceWire’s Forms tool and the optional add-on feature, SmartForms. This tool enables a trainer or manager to attach rules to an assessment that will automate training assignments based on particular answers from the assessment. Here are the steps for automating this process in the ComplianceWire LMS, using the SmartForms add-on tool.

STEP 1—Identify the Tasks That Fall Outside of a Typical Job Function

Based on the task-based CA described earlier, the trainer must define the specific competencies related to a single task, or list the actual tasks that need to be performed.

STEP 2—Define the User Group to Contain Any Individual Who Needs to Achieve This Competency

The trainer must build a group for each competency so that the training can be automatically assigned to this group. When the form is taken by the trainer and/or the employee, the response will place the learner into this group.

STEP 3—Build Curricula to Contain Task-Based Training Materials

If the corrective action involves additional training, then that training must be collected into a curricula, which can include SOPs, classroom events, a mentoring activity, online courses and other training types. This curricula can then be assigned to the group defined in Step 2.

STEP 4—Define Your Task-Based Competency Assessment

The trainer can build the CA and add rules that will place the learner into the group defined in Step 2. Because that group has been automated to receive the training defined in Step 3, this rule provides automatic workflow associated with the assessment.

STEP 5—Analyze the Results

The trainer or manager must gain the ability to view results by each question on the form, and an audit trail of all actions taken, as well as user groups affected by the form’s rules, must be available through a single report.
Conclusion

Life Science companies have long recognized the value of a competency assessment as part of a training program. From direct observation training and similar programs, the competency assessment is a critical tool for evaluating employee and contractor performance.

By leveraging tools within ComplianceWire, many of today’s leading companies can transform their task-based competency assessments into personnel’s training records, further eliminating the paper-based process, and reducing the administrative effort of trainers and managers.

What’s more, the risk-based, online CA generates more consistent results, as rules attached to the CA can be standardized, so that management gains instant visibility into skill gaps and opportunities for improving qualification requirements.

Finally, the automated CA enhances the ability of the LMS administrator to generate audit reports that capture employee qualifications related to job performance, including those critical tasks that vary by individual within a single job title.
About UL EduNeering

UL EduNeering is a business line within UL Life & Health’s Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

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.

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