Pharmaceutical Communiqué

Q4 2016

CALCULATING THE ROI OF SOP TRAINING AUTOMATION

As Life Sciences companies expand globally, opening new facilities or adding new suppliers, they face three main document and training management risks: compliance and regulatory issues, lost knowledge and change management.

This article focuses on how to address these challenges, and then measure the return on investment., of automating SOP training management by integrating a Document Management System to the Learning Management System.

(continued...)

CALCULATING THE ROI OF SOP TRAINING AUTOMATION *(Continued)*

Three Challenges to SOP Management

Regulatory Scrutiny: Global regulatory agencies, including US FDA, have made procedural control a top enforcement issue. In fact, the most cited US FDA observation of pharmaceutical companies in 2015 was "Procedures not in writing, fully followed" (21 CFR 211.22(d)).

Lost Knowledge: When most of the operational knowledge resides with a few people, organizations are at risk to lose best practices. It could take many months for a new team to define and map the governance process when crucial individuals move to new job roles, draining organizational resources and impacting operational efficiency.

Change Management: Companies are expanding rapidly, either through organic business growth or acquisition. As business areas evolve, new procedures on managing SOPs, employee qualifications, and training are being implemented.

Improving the Flow from DMS to LMS

Document management systems (DMS) eliminate many of the "paper shuffling" tasks, reducing regulatory risk and allowing document owners to devote more time developing SOPs. Automating routing of documents and version control, and easily providing a full document history, streamlines the approval and filing process.

Integrating DMS and LMS applications facilitates timely SOP management and training. Well-integrated, modern solutions improve the process, making it more efficient and effective.

When developing a governance strategy that spans both systems, organizations need to consider how it will impact existing processes and ensure the DMS to LMS integration supports the alignment approach.

Calculating the ROI of SOP Training Automation

To calculate the cost savings of automating the SOP training item creation in the LMS, we developed this case study, with these assumptions:

500 users, 200 SOPs added annually, 2,000 SOPs updated with assessments; hourly salary of $60

In this case, the Life Sciences company wanted to measure cost savings based on the amount of time employees were spending on SOP training management activities. The company did not have any DMS to LMS integration feed or application in place.

The company used the UL CWConnector tool to integrate the Veeva Vault Quality Docs® DMS with ComplianceWire®. The company wanted to know the cost savings of automating the SOP training item creation. The team calculated the hours needed to "manually" build an SOP training item, on average, and believed that the CWConnector tool freed up the team to work on other critical training activities.

The company outlined the steps for creating and updating an SOP training item, as well as the hours needed to fulfill each step.

With CWConnector, many steps, including notifying users of the new training item, were eliminated. Since the company adds 200 SOP training assignments and updates 2,000 SOP training assignments annually, it expects to save 660 hours of SOP training administrative time each year.

The savings, then, based on our assumptions, including hourly wages, are $45,600 each year by automating these steps. In addition, the automated DMS to LMS flow reduces the risks associated with improper data entry when SOP training items are manually entered in the LMS. This automation also gives administrators more time to focus on other critical activities.

Given the investment made in the applications, such an integration method can pay for the investment and generate a return on investment in six months.

The UL CWConnector for Veeva Vault

UL, with Veeva's support, has developed an integration tool that embeds governance best practices into the DMS to LMS integration. The tool, CWConnector, leverages Vault's Public APIs to enable the integration between the Veeva QualityDocs DMS and UL's ComplianceWire LMS.

To learn more, and view a demo, contact Pat Thunell at pat.thunell@ul.com.

DATA INTEGRITY:
USE OF ELECTRONIC HEALTH RECORDS

The following excerpt is from a new "Data Integrity for Clinical Research" course from UL that was released in November. Written by our partners at Raland Compliance, the course is part of UL's new Data Integrity solution for clients.

US FDA addressed data integrity in clinical trials earlier this year when the agency released Guidance for Industry: Use of Electronic Health Record Data in Clinical Investigations.

The guidance emphasizes the need for both system and process controls to support data quality and the appropriateness and completeness of patient informed consent to enable such interoperability. The guidance also explains how to use electronic health record (EHR) data in prospective clinical investigations of human drugs, biological products, medical devices, and combination products.

While the guidance is designed to help modernize and streamline clinical investigations, and promote the interoperability of EHRs and electronic systems supporting clinical investigations, it also has data integrity recommendations for clinical personnel on the use of EHR:

- Deciding whether and how to use EHRs as a source of data in clinical investigations;
- Using EHRs that are interoperable with electronic systems supporting clinical investigations;
- Ensuring that the use of EHR data collected and used as electronic source data in clinical investigations meets FDA's inspection, recordkeeping, and record retention requirements.

FDA notes in the new guidance that "use of EHRs as a source of data in clinical investigations requires additional considerations, planning, and management... Sponsors should include (e.g., in the protocol or the data management plan) information about the intended use of the EHR and the sponsor's electronic system supporting the clinical investigation. This should include a description of how the relevant EHR data are extracted and subsequently imported into the sponsor's electronic system."

Once data are extracted from the EHR into the sponsor's system, what happens when the EHR are updated? The clinical investigators must have the ability to archive and back up any EHR data that may be used for the clinical investigation so that data are not lost before the record retention period is over.

Sponsors should ensure that software updates to the sponsor's electronic system or the EHR do not affect the integrity of EHR data entering the sponsor's electronic system. Sponsors should also make sure that study monitors have suitable access to all relevant subject information pertaining to a clinical investigation as appropriate. In addition, study team access to data must be described in the informed consent materials.

The guidance on EHR data specifically states that "FDA does not intend to assess compliance of EHRs with 21 CFR Part 11," while also noting that FDA must be able to verify quality and integrity of data during on-site inspections and audits.

UL's Data Integrity program includes a specific web-based course targeted to clinical personnel, as it focuses on EHR and the growing complexity of data collection during a clinical trial.

EDUCATE YOUR ENTIRE GxP WORKFORCE ON DATA INTEGRITY

UL's Data Integrity Program

Written by industry-leading subject matter experts, our program enables companies to build awareness to the entire GxP audience, including QA, QC Lab and IT professionals.

The program includes two full-length courses, which each takes about 40 minutes to complete, as well as three "short courses" targeted to professionals within QA, QC Lab and Clinical, so they gain an understanding of how to ensure data integrity within their specific job functions.

Click here to download

QA teams can deliver these courses to as many learners as possible, to stretch their training budget and eliminate the need to develop this regulatory training content on their own, without sacrificing the quality of the training content.

The Data Integrity program includes these five courses:

- Introduction to Data Integrity
- Auditing of Computer System Validation to Ensure Data Integrity
- Data Integrity for QA
- Data Integrity in the QC Labs
- Data Integrity in Clinical Trials

Sign up for a course demo via our Essentials Demo Site.

Here you can view other Quality & Compliance Essentials sets that are available, each focused on specific topics.

Content is provided as SCORM files to host on your own learning management system.

In addition, other delivery methods are available, including AICC or hosting on UL's LMS, ComplianceWire®.

A FORMAL PROCESS FOR MANAGING CREDITS

The following article is based on the Credit feature that was added to ComplianceWire in 2016

What happens when an employee attends an outside training event - and wants to apply it to an assigned training item?

For ComplianceWire subscribers, one option is to have the learner provide a certificate, and then build an "equivalency" for the assigned training item. This moves the item from the To-Do List to the History area for that learner.

However, this process can become overwhelming to administrators if the requests start to build up. And company's policies and processes may require that managers or trainers approve all outside educational events. This requires a manual workflow, in which administrators ask for a signed approval, enter a new training equivalency, and upload the certificate into the training item record.

That's why ComplianceWire now streamlines this process with a new "Course Credit Request & Approval" feature. When this credit functionality is enabled, learners can submit a credit request, which then gets routed to "approvers" so they can grant the request and automatically remove the item from the learner's To-Do List. This worfklow also removes the burden for the learner as to how best to communicate to administrators about third-party training they attended.

Once the credit feature is enabled by UL Client Services, administrators can configure the Credit options based on the company's specific policies and processes. After a learner submits a request to approve a course credit, an authorized credit approver is notified, and can approve or reject the request from the "Action Center." Once the request is approved, a completion for the ComplianceWire Training Item is issued in the form of a Course Credit and the Training Item no longer appears in the learner's To-Do List. The feature has appropriate security permissions so individuals can grant credit to a learner.

UL recommends that when this is enabled, you should create a procedural document and communicate the requirements for Course Credits with approvers and administrators who can grant course credits. In the event of an audit, you may be expected to support the validity of course credits approved or granted.

(continued...)

A FORMAL PROCESS FOR MANAGING CREDITS *(Continued)*

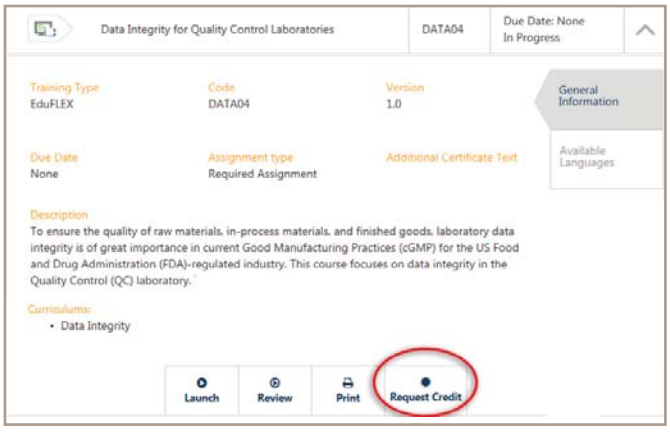
How Course Credits Work

The first step is to determine the process your company would like to apply when it comes to granting credits. Training and management teams should ask a few fundamental questions, such as:

- What job roles are expected to request credits?
- How many outside training events does the workforce attend?
- How can we validate that third-party training events provide the level of education demanded by our organization?
- Who should approve or reject credit requests: managers, trainers, or both?
- Are learners required to provide certificates or proof of training at these events?
- Should learners have to provide "reasons" for the credit request as part of the approval process?

In ComplianceWire, a manager can gain the ability to approve or reject credit requests for their direct reports. This requires that the "manager" field is populated for each learner in ComplianceWire. In addition, ComplianceWire enables you to build a User Group of "Credit Request Approvers."

When the Credit feature is enabled, a learner can visit the To-Do list, click an assignment's arrow button and make a request for credit, as shown below:



When the learner submits the credit request, he or she must select a reason, and the list of reasons can be managed by administrators. Learners may be required to upload a certificate or proof of training. Note: this does require that clients have subscribed to our Shared or Dedicated Hosting service.

When the learner makes the request, the status changes to "Credit Requested" for that item, as shown below.

The request then displays in the designated approver's Action Center as "Credits Pending Approvals." The number of approvals pending is also displayed. The approver can then approve or reject the request.

Capturing Credit Activities

For auditing and management visibility purposes, an event log entry is created in ComplianceWire when a Course Credit is Approved, Granted, Rejected, or Removed.

Also, an event log entry is created for every action associated with managing the Credit Reasons: add, edit, disable, and enable.

Additionally, administrators that have security permissions to view Users or Training Items can also view the associated Credit History.

To learn more about the Credit feature, send an e-mail to your Senior Sales Director or send an e-mail to Client Services at prn.technologyservices@ul.com

BUILDING A SKILLS DEVELOPMENT FRAMEWORK

The following article is an excerpt from a piece written by our Aseptic Processing expert, Ann Early, published in September 2016.

If your company manufactures sterile products, it would seem unimaginable for these events to happen:

- Operators on all fours crawling on the floor under the filling line during routine aseptic filling operations adjusting or removing vials from the line wearing gloved hands rather than restricted access barrier system gloves
- Poor facility and equipment design inadequately protecting the sterile product during manual manipulations, posing a substantial hazard to product sterility and an unreasonable risk to patient safety
- Failure to follow appropriate written procedures specifically designed to prevent microbiological contamination of drug products purporting to be sterile, and that require validation of all aseptic and sterilization processes

The events represent actual US FDA investigator citations typical of what companies operating in a sterile manufacturing environment would see as 483 observations during a routine FDA inspection.

The FDA expects sterile drug and device manufacturers to maintain a keen awareness of the public health implications of distributing non-sterile products. Poor and lax current Good Manufacturing Practice (cGMP) conditions at a manufacturing facility can ultimately pose a life-threatening health risk to patients. As a result, the Agency provides guidance to help companies meet the requirements in its cGMP regulations (2l CFR parts 210 and 211) when producing sterile products using aseptic processing.

It's no coincidence that aseptic processing, along with environmental monitoring and sterilization, represent three of the FDA's top 10 areas of ongoing scrutiny for organizations operating cleanrooms. Training ranks a close fourth. Yet, despite its relative importance for building and sustaining the competencies that support regulatory compliance and risk mitigation, training is often a topic that suffers from a low priority among the executive team and the resource allocation pecking order.

This could be attributed to perceptual and operational hesitancy in the sterile manufacturing space, since developing an effective skills training program takes time, funding, and:

- Requires indirect human capital to develop the course curriculum and analytics
- Can be more complicated than originally projected
- Suffers from a misperception about the value of the skill sets needed
- Is impacted by an institutionalized "re-train" mentality that offsets investing in a long-term development solution that elevates learning, engagement, and performance

BUILDING A SKILLS DEVELOPMENT FRAMEWORK *(Continued)*

With regulatory enforcement becoming more stringent, the days of cleanroom operators performing tasks by rote, or executing them incorrectly because that's how their predecessors did it, are over.

More organizations are concluding that it's time to drill down deeper – beyond SOP training and OJT checklists – and define more formal competency mapping.

Skills development programs serve as foundational elements of these "critical to quality" initiatives. In addition to helping organizations remain compliant with the FDA and other regulatory agencies, a well-designed competency-based aseptic training program addresses business issues, such as reducing work stoppages, compromised product sterility, and risk exposure from global agency observations.

In addition, a skills development program can improve performance, productivity, and quality for competitive advantage, and also raise workforce morale and motivate the pursuit of excellence.

Here are the seven steps of a skills development framework:

1. Assess each role within the area, and walk through the processes that each role interacts with.
2. Define the skill levels and competency levels for each job function.
3. Align similar roles, similar competencies, roles to competencies, and other relevant company scales.
4. Develop role-based training programs, curricula, and technical competency models.
5. Implement and deliver both training programs and technical competency programs.
6. Track and report qualifications to these programs, identify skill and competency gaps, and drive training that closes these gaps.
7. Monitor skill and competency development, evaluate if progress is on track, and adjust accordingly for each employee, team, unit, department, and physical location.

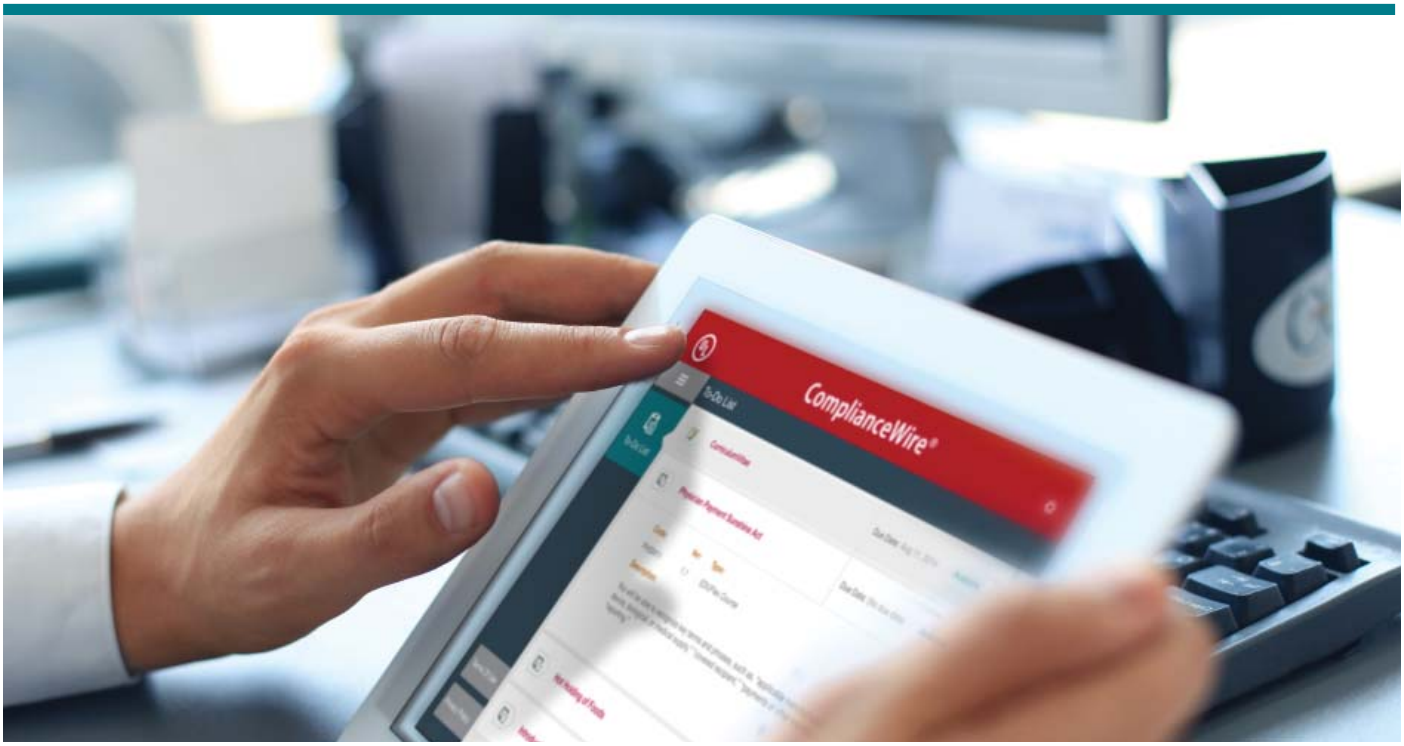
UL Aseptic Processing Competency Solution

UL's Aseptic Processing Competency solution includes hands-on GMP consulting expert Ann Early to work alongside your QA, Training, HR and Operations teams to build a program that's based on proven best practices.

These steps map relevant, competency-based actions that need to be conducted for each job function. Companies can achieve compliance while improving business performance, and also drive these improvements:

- Greater employee knowledge related to the basics of microbiology, aseptic gowning, and aseptic behavior
- Increased employee engagement through well-defined roles and job functions
- Understanding of measurement best practices, such as incidence rate of personnel monitoring and production line environmental monitoring failures, deviation reports, and lot rejection rates
- Improved gowning and aseptic behavior

To learn more about our Aseptic Processing Competency solution, contact Pat Thunell at pat.thunell@ul.com.



About UL Compliance to Performance

UL Compliance to Performance (formerly UL EduNeering) 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. Its more than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

For more than 30 years, UL Compliance to Performance has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL Compliance to Performance 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.