Technology's Role in Improving SOP Management Processes

UL | Veeva

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Executive Summary

As the industry faces increased globalization, product supply chain complexity, and regulatory enforcement, Life Sciences companies need to demonstrate to auditors that they are in full control of their GxP document and training management programs.

A UL study revealed that 50% of 483 CDER observations in 2015 were procedural related, with "Procedures not in writing, fully followed" (21 CFR 211.22(d)) as the most cited observation for pharmaceutical companies by FDA investigators. With regulatory agencies increasing focus on GxP procedural issues, organizations need to improve document management and training record management.

Many companies have invested in "best-of-breed" Document Management Systems (DMS) and Learning Management Systems (LMS). For greater visibility and consistent operation, a DMS and LMS governance model is often established to define critical business processes including: how to apply nomenclature, use system security roles, and manage impact from new releases. When these applications are well-integrated, it makes it easier for organizations to enforce good governance, and streamlines the document creation, review, and approval to training distribution and receipt process.

In this paper, we will discuss how advanced, cloud-based DMS to LMS integrations can simplify the governance model for Life Sciences companies. With an integrated solution that supports well-defined administrative rights and targeted training groups, and accelerates key document creation to training processes, companies can gain the following benefits:

Improved retention of procedures

More time devoted to SOP development and maintenance

Streamlined SOP management

Greater visibility into compliance

Reduction in Training Management effort

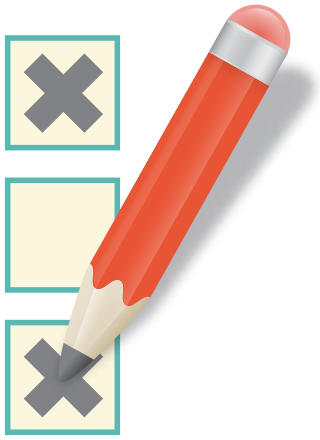
Less IT maintenance

Reduced risks related to regulatory inspection observations

Eliminating SOP Management Risks

As Life Sciences companies expand globally, opening new facilities or adding new suppliers, they face three main document and training management risks.

1. Compliance



The first, and perhaps the most costly risk, is compliance. 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)).

2. Lost Knowledge

The second risk centers on "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.

3. Change Management

The third risk is 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. For example, a remote team may define their own nomenclature for SOP management and related training items, or create their own policies for departmental visibility into training management. Siloed processes threaten the ability of the quality assurance team and senior management executives to gain visibility into the state of quality compliance across multiple product lines and facilities.

When companies add new people to a process, a governance strategy that captures and enforces key policies and operational rules is critical to success. A DMS to LMS workflow requires such a policy. Key document owners at Life Sciences companies need the ability to access, review, approve, distribute, and assess competency on SOPs and other controlled documents. They also need defined rules for establishing learner groups and managing training. The DMS to LMS process demands feedback from stakeholders including documentation personnel, subject matter experts, and department and training managers.

Governance Model Spanning DMS and LMS Applications

Many leading Life Sciences companies have defined governance models based on these key areas in document and training management policies:

1. SOP Management Policy: Focuses on document creation and SOP reviewer responsibilities, nomenclature, and definition of stages including: Pending, Approval, and Effective definitions:

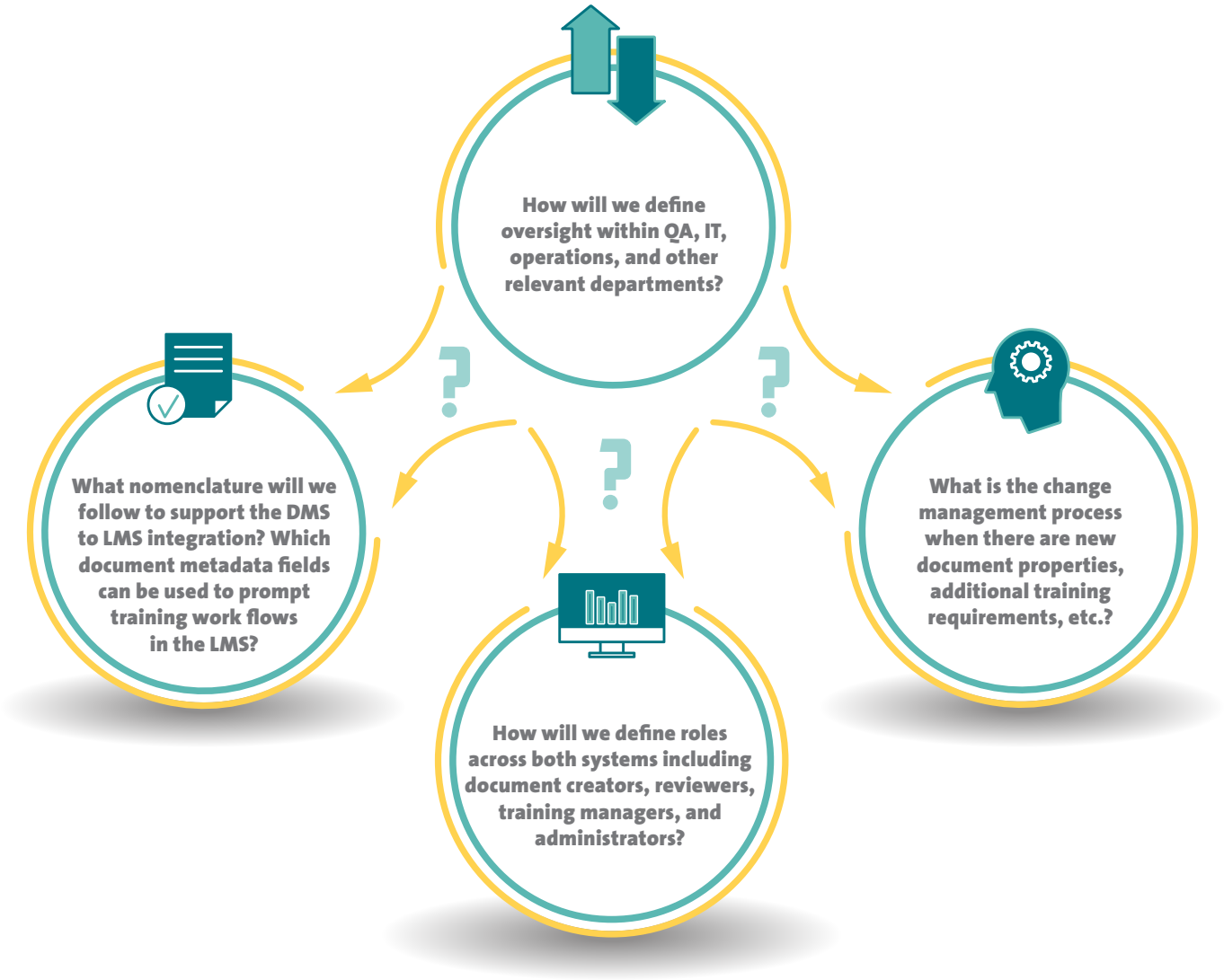
2. Training Policy: Describes scope, training responsibilities, procedures for GxP trained and non-GxP personnel, training curricula, training documentation, annual GxP training, and external training;

3. Use and Operation Procedures: Instructions for administrators, managers, and other roles for general use and operations.

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. Cloud-based DMS applications enable document owners to securely collaborate — in real-time — with authorized employees and partners anywhere in the world, speeding up the document review and approval 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. There are four types of "system governance" questions commonly asked during the design phase:



A governance strategy that accommodates GxP and non-GxP departments allows better operational alignment and efficiencies. It harmonizes document and training processes in multiple areas such as quality assurance, clinical, labs, and R&D — facilitating continuous improvement and knowledge management across the organization.

The effectiveness of the integrated DMS to LMS solution will shape the company's vision on managing critical content — driving regulatory compliance and improving business efficiencies.

Improving SOP Management: Top Ten Capabilities of Seamlessly Integrated DMS and LMS Solutions

With today's technology advances, companies can leverage best-of-breed DMS and LMS applications to enable seamless SOP management and training. Improving productivity of all job roles involved in the process, the top ten capabilities of well-integrated, modern solutions include:

1. Real-Time Integration The LMS immediately detects document and metadata changes in the DMS — new document version, document title change, etc. Based on the type of change, LMS automatically initiates workflows for new training assignments or for trainers to review the training item. Real-time integration offers advantages over a daily file-based batch import as it accelerates the time from when training impacted content is created or modified to in-use — minimizing compliance risk and increasing operational efficiency.

2. Training Item Status Flow The DMS to LMS integration supports taxonomy mapping, enabling critical document metadata fields to automatically trigger LMS workflows. For example, if a DMS document has a "pending" status, the training manager is allowed to add an assessment — via the LMS — before making it an "approved" document. Version updates is also automated, enforcing new training assignments for targeted learners, when there are new or modified SOPs.

3. Flexible System Security Roles: Administrative, Approver, Learner Systems allow proper definition of security roles in the DMS and LMS. For example, an LMS administrator with the proper security profile can define training rules such as including an item in a curriculum and adding a retraining period, or a quiz, etc.

4. Alternative Training Items The LMS stores a "link" to the source controlled document in the DMS and allows the addition of a classroom event or assessment, which links back to the original SOP training item.

5. Audit Trails All document activities, including learning and compliance tasks or actions, are logged in detailed audit trails from content creation, review, and approval to training completion and assessment.

6. Rapid Implementation Time Cloud integrations have faster implementation times than legacy solutions. Companies just need to configure the integration to align the DMS and LMS, enabling employees and partners to accelerate content creation, sharing, and training.

7. Ease of "Change Control" With minimal IT involvement, the solution is easily modified to support downstream workflows when metadata in either the DMS or LMS change. Reducing change control costs is a compelling advantage of cloud-based applications over legacy integrations, such as an HTTPS Post Interface, which requires the IT team to manage and maintain business logic.

8. Accelerated Validation Companies are always on the latest release with multitenant cloud. Applications designed for regulated industries simplify validation and facilitate compliance — performing IQ/OQ, and providing test scripts and other validation documentation on the integration with each release.

9. Ease-of-Use Modern, integrated cloud solutions have a consumer web design driving higher user adoption, and provide a seamless user experience throughout the content creation, review, and approval to training and assessment process. It is also easier to train employees and partners, speeding up onboarding time.

10. Visibility into Compliance Risk Operationally aligning the DMS and LMS solutions enables greater visibility into compliance and risk. Organizations can see which SOPs have been created yet not trained on, or determine which SOPs have poor assessments and track performance with new versions of the critical document.

Conclusion

Companies that invest in a governance model overseeing both DMS and LMS applications facilitate operational alignment. This is crucial for continuous process improvement and knowledge management across the organization.

Leveraging modern technology that has many key capabilities, companies can easily support best practices for integrated DMS and LMS solutions. Gaining many benefits including efficient administration, accelerated change management processes, and improved productivity of all employees involved in the content creation to training workflow — organizations can dedicate more time to developing critical SOPs and fostering training effectiveness.

With more control over governance processes for integrated DMS and LMS solutions and improving SOP management, Life Sciences companies can assure stronger adherence to global regulatory requirements.

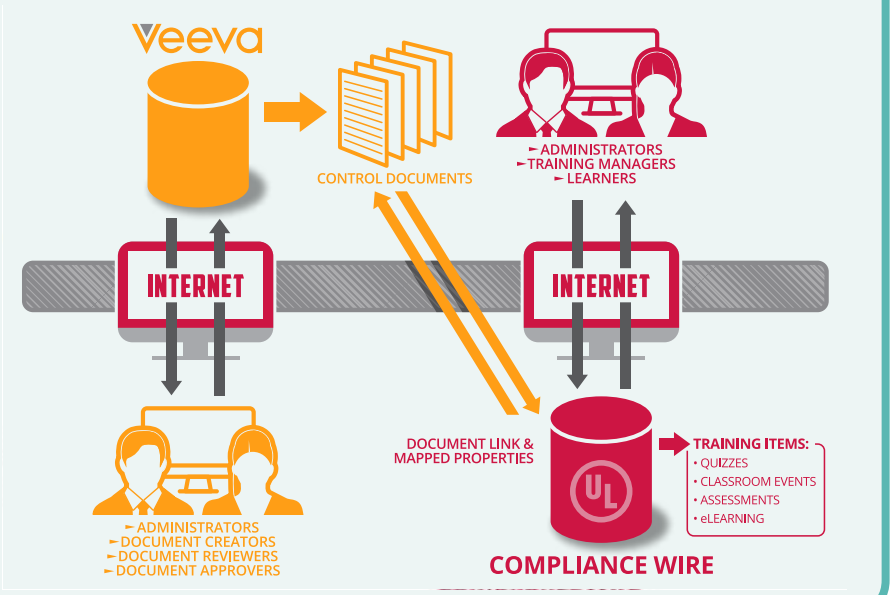
Integrating Veeva Vault QualityDocs with ComplianceWire

The UL team, 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 document management system and UL's ComplianceWire learning management system.

After the CWConnector is enabled for a client, the tool detects document and metadata changes made in Vault QualityDocs such as a new document version, document title change, etc.

CWConnector then updates the corresponding "training item" for that document in ComplianceWire. For a new controlled document in Veeva, the equivalent training item is established in ComplianceWire.

The LMS administrator can define training rules, such as including training items in a curriculum, adding a retraining period, adding a quiz, etc. When the learner receives the training item assignment, he or she clicks a link that "displays" the actual electronic file that resides in Vault QualityDocs. The Vault QualityDocs and ComplianceWire integration ensures that all document activities, as well as learning and compliance activities, are logged in detailed audit trails that extend from content creation, review, and approval to training and assessment.



About Veeva Systems

Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 500 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices in Europe, Asia, and Latin America. For more information, visit www.veeva.com.

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About UL Compliance to Performance

UL Compliance to Performance 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. 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. More than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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