10 Insights about Learning Management with SharePoint in Highly Regulated Industries

This e-book addresses the challenges of training management in highly regulated industries such as health care and pharmaceuticals. The same concepts apply directly to regulated industries such as financial services and insurance. If your company requires training participants to certify standard operating procedures (SOPs), adhere to a post-hire training and certification schedule, and ensure follow-up if training and certification dates have been missed, this e-book addresses your challenges and offers solutions.

For organizations that are committed SharePoint users and those that have decided on SharePoint as their corporate Enterprise Content Management Solution, a SharePoint-based LMS is the learning management system (LMS) of choice.

Introduction

Selected industries such as health care, pharmaceuticals, financial services, and insurance experience a level of government regulation and oversight not seen in other sectors. This regulation and oversight exists to ensure that quality is built into the products and services that, lacking such quality, would prove harmful when directly or ultimately consumed by the public.

Forward-thinking regulated companies seek the quality carrot, not the regulatory overseer's stick. They develop and sustain a culture of quality. One aspect of regulated company quality is ensuring use of validated software in application solution stacks performing regulated functions. Validation is a complex, risk-driven undertaking that focuses on eliminating procedural and functional risks in software used to support regulated processes. Managing regulated content is one of those regulated processes.

For managing regulated content, an ever-increasing number of organizations have adopted, or are planning to adopt, Microsoft SharePoint. Microsoft has done extensive work to prepare SharePoint for validation approval. Out of the box, SharePoint simply needs a mission-appropriate architecture and configuration to be specified and it is ready to undergo its validation process.

Part of the regulated content managed by SharePoint is training content. Training content is used to educate company personnel about standard operating procedures (SOPs). The training material must be distributed to the right individuals, at the right time, with appropriate acknowledgments collected, electronic signatures captured, and test results archived.

With the addition of a learning management solution (LMS) that integrates with SharePoint, training management professionals are able to control the cardinal aspects of training. The right SharePoint-based LMS makes use of already-validated authentication, security, content access, and similar services. This means a huge savings in time, effort, and expense. The right SharePoint-LMS fusion will only need a change control configuration management process that is much simpler than full validation.

ShareKnowledge™ is such a SharePoint-based LMS. For quality managers, training managers, and IT managers, ShareKnowledge™ offers an unbeatable combination of deep SharePoint integration and out-of-the- box training management capabilities that helps make high-quality training an everyday reality.

Key Findings

1. Microsoft SharePoint (SharePoint) offers an excellent mix of document management and related capabilities that help companies, especially those in regulated industries, manage critical content.

2. SharePoint adoption is accelerating in regulated industries.

3. SharePoint typically undergoes computer system validation (CSV), a process for determining that a computer system is valid for its intended use in a regulated environment.

4. Once validated, effective change control processes ensure SharePoint maintains its validated status over time, such as when SharePoint-based applications are integrated into the validated SharePoint environment.

5. Standard operating procedures (SOPs) are a major part of SharePoint's content in regulated industries, as well as tests, and related training content.

6. Training management using SOPs is a high-value use case for SharePoint in regulated industries. Training management is the maintenance, scheduling, and delivery of training, and follow-up for SOPs stored in SharePoint.

7. Learning management solutions (LMSs) are application suites for training management.

8. LMS developers should specifically design their products to leverage the already validated SharePoint installation as an infrastructure for corporate learning. Validated SharePoint capabilities include services such as authentication, security, and content access.

9. Combining an LMS and SharePoint is a best practice for training managers, quality managers, and IT managers. It confers some critical advantages over stand-alone LMS solutions, including rapid time to training value, control over electronic signatures, and SOP test results. The right LMS-SharePoint integration also avoids another round of CSV, relying instead on change management controls.

10. ShareKnowledge™ is a SharePoint-based LMS that makes full use of validated SharePoint services and the training content already stored within SharePoint.

Analysis

Every regulated organization wishes to avoid entanglement with its regulatory agencies, and those with consistent governance and oversight may avoid problems. However, the situation is more serious for managers in regulated industries when inspectors find problems. This analysis considers that situation.

Regulatory agencies such as the U.S. Food and Drug Administration (FDA) inspect regulated industry participants' facilities and processes to identify conditions and activities that might violate the Food, Drug, and Cosmetic (FD&C) Act and related acts. Suspected violations are presented to organization management in written prioritized form as an FDA-483 citing observed violations.

According to the FDA, "Companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and then implement that corrective action plan expeditiously." (FDA)

Companies so cited may propose "**additional training for personnel**" (Noferi, 2002), and state that they will "**provide additional learning activities to ensure enhancement of our staff's knowledge regarding the quality system elements**." (Tsung, 2012)

Additional training and learning must be effective. If the FDA finds otherwise, they will escalate their oversight with a warning letter, **published without redaction on the www.fda.gov website. Therefore, training managers, quality managers, and the IT organizations that support them must ensure they can rapidly deliver on their company's FDA-483 response. This assurance must be backed up by action.**

Training managers will face challenges that include:

- Rapidly converting promised additional training and learning activities into actiona44ble plans;
- Recording and maintaining electronic signatures that authenticate training participants' acknowledgment of "read and understood," and certification of test-takers' identities;
- Ensuring their learning management solution meets fundamental auditing, tracking, and data lineage requirements;
- Managing additional re-testing requirements arising from passage of time, standard operating procedure (SOP) updates, and imposition of new SOPs.

Training managers are likely to depend on IT solutions to ensure effective training delivery:

- These solutions must be validated according to appropriate Good Automation Manufacturing Practice (GAMP) standards developed by the International Society for Pharmaceutical Engineering (ISPE) before they can be used for regulated training purposes.
- IT solution GAMP certification is a lengthy, complex, and costly risk-based assessment and assurance process that will examine IT solution change control, data integrity, metadata management, data lineage control, and audit capabilities, among others.
- "Today, almost every life sciences company uses [Microsoft] SharePoint as a general purpose collaboration and content management tool. However, NextDocs' second annual State of SharePoint in Life Sciences Survey reveals a dramatic expansion in use of Microsoft SharePoint to manage regulated content in validated systems." (NextDocs, 2012)
- Microsoft SharePoint (SharePoint) is classified as a Category 4 "Configured Off the Shelf" solution under GAMP, meaning that Microsoft has already done much validation work for SharePoint. Remaining validation focuses on installation and configuration of SharePoint, with follow-up change management control to ensure continued validation as the SharePoint installation evolves.
- SharePoint validation is inherited by software solutions designed to integrate with SharePoint. In this context, training management solutions that are SharePoint-based and use validated SharePoint services can follow the simpler, faster, and less-costly change management control process rather than a full validation.
- Training managers, quality managers, and IT organizations will all benefit from maximizing re-use of existing investments in already-validated IT solutions to ensure rapid, effective, and compliant training.
- ShareKnowledge™ LMS is an industry-leading LMS that does inherit existing SharePoint validation of critical services and will avoid the need for another time-consuming and costly validation. ShareKnowledge™ needs only the much simpler change control configuration management process.

Today, SharePoint provides regulated content management for many companies in highly regulated industries. With ShareKnowledge™ onboard, your industry-leading integrated training management solution is ready for action.

Recommendations

This recommendations section focuses on SharePoint, the learning management solution (LMS) ShareKnowledge™, and how together their whole is greater than the sum of the individual parts.

About SharePoint (SharePoint)

- SharePoint (SharePoint) will meet the CFR 21 Part 11 requirements with a combination of technical controls and procedural controls.
- SharePoint must be configured to be CFR 21 Part 11 compliant. For example, audit trails must be turned on and security must be set up.

About Documenting SharePoint Validation

- **Always maintain effective change control processes of validated "Configured Off the Shelf" solutions** such as SharePoint (SharePoint). This will simplify the task of maintaining a validated status.
- **Create a traceability matrix of configuration settings for SharePoint** that will be maintained throughout the life of the system to demonstrate that SharePoint remains compliant over time.
- **Documentation like this should link test scripts to functional requirements** so regulators can see how functional requirements have been met and continue to be tested and validated.
- **Ensure good documentation practices that follow ALCOA,** which means Attributable, Legible, Contemporaneous, Original, Accurate.

About SharePoint and LMS Integration

Quality managers should note the value of integrating a learning management solution (LMS) with content management. The efficiency of distributing training content already under Enterprise Content Management (ECM) should be clear.

Remember that ShareKnowledge™ is an LMS that makes training management simple in a SharePoint environment. Many regulated industries use SharePoint for ECM, so ShareKnowledge™ helps to distribute training material and organizes training.

If your regulated company has selected SharePoint for content management, then an integrated LMS such as ShareKnowledge™ is critically important as a solution in your quality and training management suite.

ShareKnowledge™ is an effective training management solution for those organizations that have implemented SharePoint for regulated purposes. It is simple to validate ShareKnowledge™ as the organization's learning management solution (LMS) and ShareKnowledge™ installs in SharePoint using already validated authentication, security, and content access services.

The validation of ShareKnowledge™ in the SharePoint environment is simpler because ShareKnowledge™ uses already validated services. Instead of a full validation, this can be a change control configuration management process.

ShareKnowledge™ allows you to use already existing documents for training; there is no need to move documents between systems. This means fewer security risks and challenges.

The whole SharePoint content repository, including training material, is already shared in SharePoint libraries and is under version control. This is a benefit for organizations that already have large amounts of content and are using SharePoint to manage organizational knowledge. Now they can use ShareKnowledge™ for training too.

When SharePoint and ShareKnowledge™ are integrated, all training materials reside in the same system. If an SOP changes, it is simple to distribute the updated SOP to all interested parties.

SharePoint and ShareKnowledge™ together offer an unbeatable total cost of ownership (TCO). Adding ShareKnowledge™ to work as a part of SharePoint gives regulated companies a holistic Enterprise Content and Learning Management solution with benefits much greater than the sum of its parts.

Beyond low TCO, there are many additional benefits to consider. These include strategic, enterprise system integration, information integration, and operational ease of use. All of which mean great functionality with low TCO. Please ask us for our TCO e-book, titled "**SharePoint-based LMS Total Cost of Ownership**", to learn more.

Conclusion

Regulated industries are adopting SharePoint as their Enterprise Content Management solution at an ever-increasing rate. SharePoint was designed by Microsoft to facilitate out-of-the-box validation. A common thread among regulated companies is their need to ensure that relevant personnel receive standard operating procedure (SOP) training, and that the record and results of that training are properly archived for possible inspector audit. SharePoint is a fine repository for training content.

With the addition of an integrated learning management solution (LMS), the scheduling, delivery, monitoring, results collection, and testing follow-up for SOP training are controlled by training management and deliver results to quality management. ShareKnowledge™ is an LMS designed specifically to integrate with SharePoint, and it makes full use of all of the SharePoint-validated services configured for your regulated organization.

About ShareKnowledge

ShareKnowledge is a corporate learning management system built on top of the Microsoft SharePoint platform. ShareKnowledge exposes every benefit of SharePoint for learning professionals as well as integration with popular webinar services and course schedule integration with your Outlook calendar, or other e-mail clients that support iCalendar. ShareKnowledge was designed to integrate directly and completely with SharePoint, and builds on all existing SharePoint administrative efforts such as Active Directory integration for permissions and security.

To find out more about SharePoint, ShareKnowledge, and how they work together to deliver the best learning management available today, contact us.

Author

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