WHITEPAPER

Simplifying and Improving Audits:

A Strategy for Life Sciences Organizations

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Audits are inevitable facts of life for life sciences firms of all types and sizes. Pharmaceutical companies, medical device manufacturers, biotechnology firms and contract research organizations are subject to audits and inspections from regulatory agencies, customers, sponsors and prospective clients. The results of these audits can significantly impact an organization's ability to remain competitive and attract new business.

Often facing numerous audits per year, life sciences companies are challenged to produce, in a timely manner, the documents, process verifications, evidence of corrective actions requested by auditors and more — all while still remaining focused on the core business at hand.

This ongoing struggle can be greatly eased, however, by simplifying the processes used for managing content, tasks and reporting activities associated with audits. Doing so will save life sciences companies time and effort, increase their productivity and competitive advantage and reduce the likelihood of them receiving critical audit findings, regulatory warning letters and other similar negative outcomes that can damage a company's reputation and result in other adverse impacts on the business.

The Nature of Audits and the Challenges They Present

In one example of a typical life sciences company audit, the auditor will visit the premises, meet some key personnel, ask to see various standard operating procedure (SOP) documents, and request evidence that these SOPs are being followed. The auditor makes a "finding" when he or she observes a gap or inconsistency between the company's SOP for a particular process and the way it was actually executed. Then, of course, the audited company must take corrective actions, as well as actions to prevent a recurrence, in order to reconcile the finding.

This entire audit process is made more difficult, stressful and complicated by the following all-to-common unfortunate scenarios:

- The company's audit point person does not effectively communicate to his or her team that an audit is scheduled, resulting in inadequate time for the team to prepare.
- Once the audit is underway, producing the requested and required documentation and content for the auditor is time consuming, usually because the individuals searching for it must sift through a network of countless folders that can be scattered across various individual computers and company shared drives in order to eventually locate it. Once the required documentation is found, the versions may be incorrect, and more time must be spent verifying the accuracy of the documentation.
- The auditor determines that an inadequate process exists to verify that all individuals who are required to review and approve an SOP or other documentation have indeed done so.

- The company relies much too heavily on email to communicate pending tasks, training directives and reminders, SOP changes, corrective actions and other audit-essential information to employees. Email cannot ensure that information and directives were ever actually read by their intended recipients or acted upon. The potential for communication failure and process breakdown in this situation is tremendous.
- The company relies on an extremely tedious manual process for verifying whether specific tasks are completed by their deadlines.
- The company cannot verify that confidential information is available only to authorized employees.

These scenarios tend to result from an organization's lack of a formal strategy and a system in place for managing audit-related information and processes. Instead, documents, information, processes, SOPs and so on are often kept in a complex and chaotic maze of network folders and email threads.

The Solution: Streamline and Simplify Audits with Enterprise Information Management

Many life sciences companies have substantially simplified and improved their audit processes by leveraging an enterprise information management (EIM) system. Effectively using an EIM system can take companies from a place of unmanageable folders, documents and email to a highly controlled, transparent system for managing content, processes, tasks and workflows in a manner that can be tracked and verified by auditors.

The first step on the path toward a more streamlined (and less painful) audit process is selecting an EIM system that is flexible and can be configured to meet specific organizational needs. The ideal EIM system will provide the ability to track and control all content and associated processes with metadata, along with the ability to personalize or customize the system by job, role or according to individual preferences. Instead of a quality manager needing to "hunt down" information for an audit from various folders, spreadsheets or other various systems and information silos, the information will be automatically and dynamically presented to that manager based on certain characteristics and criteria as defined by metadata. The required content will, in effect, "find the individual."

An EIM system will also ensure that sensitive and confidential information assets are automatically visible only to authorized users—without the necessity of constantly asking the IT department to set and reset access permissions.

Processes for updating and verifying staff training, which are of crucial importance to heavily-regulated life sciences companies as well as being notoriously difficult to manage, represent yet another area in which an EIM system can come to the rescue. Reliance on email reminders to ensure employees are completing their training obligations simply doesn't work; a more automated and verifiable system must be in place in order to prove to auditors that all staff certifications and learning requirements have been met. By leveraging an EIM solution, users can easily view their training requirements, track their progress toward meeting learning objectives and receive reminders when key training-related deadlines are approaching.

For example, an EIM system can automate the process of notifying employees when a new or updated certification is needed, as well as capturing employees' 21 CFR Part 11-compliant electronic signatures to verify that related documents have been read and understood.

Similarly, a metadata-driven EIM system can automate processes for verifying that tasks of all kinds are completed by the right people at the right time. Task assignments are automatically generated for individual users within the system with corresponding alerts, such as email notifications, to enhance communication. As tasks are completed, the system collects the evidence and archives it in such a way that it can be easily retrieved for an auditor at any time.

For example, if a biotechnology firm has a mass spectrometer requiring monthly maintenance, the instrument can be documented in the EIM system to easily automate and manage the scheduling of related maintenance tasks. In this case, a monthly maintenance task, such as calibration, is assigned to the appropriate laboratory technician, who also receives a corresponding separate email notification. A configurable time period can be defined for which the task will remain in the technician's to-do list. If no action is taken, the task will then proceed automatically to the next workflow state defined as "overdue/escalated." When a task is finished, it is easily closed with an electronic signature and the manager is notified. This provides an easy means of capturing the evidence for the auditor.

Finally, the EIM system can be configured to automatically record and save all audit findings, while also ensuring the right people have access to this information. Findings are linked within the system to related content and individuals, rather than hidden within spreadsheets, written documents or emails.

An EIM system that leverages metadata is key to streamlining and simplifying audits. Because it classifies information based on what it is, rather than where it is stored (as with folders), metadata enables and streamlines all functions of the EIM system: searching for information, instruments or persons; displaying and reporting information; setting permissions; sorting content; generating workflows; personalizing to-do lists—and more. This metadata is extremely powerful in that it organizes information, associates it with related data and controls it.

Simplified Audits = Reduced Risk

For life sciences organizations that are busy contributing to medical breakthroughs and improved human health worldwide, undergoing audits is a so-called "necessary evil," but one that can be made significantly more efficient and less stressful by moving from an antiquated, and often completely manual, system of files and folders to a comprehensive, automated EIM system. Further, by exploiting the power of metadata within such an information management system, life sciences organizations can:

- ensure the requested versions of documents are quickly and easily accessible
- better manage workflows and verify task completion
- ensure sensitive content is accessible only to authorized users
- streamline and automate staff-training notifications and verifications of completed training
- automatically collect evidence and make it easily accessible during audits
- record and save all audit findings and direct them to the correct personnel for processing

Taking advantage of an EIM system significantly assists life sciences organizations in adopting and executing these best practices for simpler, more successful audits, improved communication and efficiency and, ultimately, better business.

About M-Files Corporation

M-Files enterprise information management (EIM) solutions eliminate information silos and provide quick and easy access to the right content from any core business system and device. M-Files achieves higher levels of user adoption resulting in faster ROI with a uniquely intuitive approach to EIM that is based on managing information by "what" it is versus "where" it's stored. With flexible on-premises, cloud and hybrid deployment options, M-Files places the power of EIM in the hands of the business user and reduces demands on IT by enabling those closest to the business need to access and control content based on their requirements. Thousands of organizations in over 100 countries use the M-Files EIM system as a single platform for managing front office and back office business operations, which improves productivity and quality while ensuring compliance with industry regulations and standards, including companies such as SAS, Elekta and EADS.

For more information, visit www.m-files.com