OPENTEXT™

OpenText in Life Sciences: Quality Document Management

Achieving operational efficiencies and compliant document management to minimize risk and allow faster time to market has never been more critical for Life Sciences.

Adhering to a high standard of quality in processes, products and functions throughout a Life Sciences organization is a complicated and highly dynamic responsibility. Lack of visibility into your quality systems can lead to issues being overlooked or mishandled. Deviations from quality standards quickly affect the bottom-line performance of your organization and your company. The result: you suddenly find yourself out of compliance with standards and procedures.

Introduction

All companies that develop new products are interested in reducing the time that it takes to get their products to market. For Life Sciences companies, the challenge of reducing time-to-market for new products is even greater than for other industries due to the strict regulatory environment in which you must operate. Quality groups are under strict directives to comply with the electronic records provisions of FDA 21 CFR Part 11, while addressing the needs for Pharmaceutical Best Practice (21 CFR 210 and 211), Biologics Best Practice (FDA 21 CFR 600-680) and Medical Device Best Practice (FDA 21 CFR 820). Often, these records are managed in disparate information silos, slowing the flow of information among stakeholders and impeding time-to-market. In fact, poor documentation procedures are the most cited reason for receiving a 483 Warning Letter from the FDA. Thus, a truly comprehensive Quality Document Management solution consolidates and maintains your business-critical documents in a manner which complies with your corporate and international regulatory guidelines and by makes those documents available to the right internal and external stakeholders at the right time.

Historically, Life Sciences companies have managed and tracked documents in paper format. The methods and practices for ensuring that the paper records included in submis-

MAINTAINING CONSISTENT QUALITY AND REGULATORY COMPLIANCE

The OpenText Quality Document Management solution is used in conjunction with robust SOPs to help Life Sciences organizations comply with the myriad of regulations and global industry standards, including:

- *Current Good Manufacturing Principles (cGMP)*
- *EU Annex 11*
- *FDA 21 CFR Part 11*
- *FDA 21 CFR Part 211*
- *FDA 21 CFR Part 820*
- *Good Automated Manufacturing Principles (GAMP)*
- *Good Documentation Practices (GDP/GDocP)*
- *ISO 15378:2011*

"81% of 483 Warning Letters issued by the FDA are directly attributable to quality documentation issues."

sions or maintained for possible inspection were authentic and unaltered were well established and understood. Substituting electronic documents and signatures for paper required new procedures to insure authenticity, integrity and confidentiality.

A Quality Document Management solution for Life Sciences helps you achieve the highest product quality while maintaining compliance across all your key processes and systems. Move away from error-prone paper-based systems and automate your manual review and approval methods reducing the risk of non-compliance. OpenText offers electronic forms and workflows that let you automate the entire process of creation, review, and approval of quality documents such as SOPs. Generate on-demand reports that provide up-to-the-minute details and visual indicators on the status of all quality tasks, processes, and documents. Detailed 21 CFR Part 11-compliant audit trails, easy retrieval of information, and electronic signatures ensure you'll have all the information required to respond to inquiries.

How OpenText helps manage your Quality Systems

The OpenText Quality Document Management solution lets you quickly and easily track and manage documentation from all your different quality systems. CAPAs, NCPs, Deviations, Audits, and other information can be easily accessed via the web-based interface from anywhere in the organization or anywhere in the world.

Collaborative Workspaces allow you to manage each quality system individually yet maintain visibility across all quality systems in one central location. OpenText ensures security, which lets you control access to the different workspaces, allowing users to see only the information that is required for their respective roles or job title.

Electronic forms make creation of new quality records quick and easy. Any type of form can be recreated electronically, removing the need for paper forms. The form is filled out in the browser, saved, and then automatically routed for review, processing, and approval. Any subsequent changes are captured in the version history and audit trails.

The workflow functionality in the Quality Document Management solution allows users to model any quality process via configuration, negating the need to re-validate the entire application. The graphical workflow builder lets you drag icons representing different tasks and roles onto the palette. You then quickly connect the tasks in the proper sequence, either sequentially or in parallel. Automated decision steps can be put in the process, speeding review, along with electronic signature requests.

At the completion of the quality process, all information is stored in the repository where it is indexed and fully searchable. Past quality records are easily retrieved and viewed online. A number of standard reports are provided, and custom reports can be created. Reports can be retrieved in real-time or run on scheduled intervals.

OpenText Content Suite

Serving as the foundation of Quality Document Management, OpenText Content Suite (formerly known as LiveLink) is a highly scalable, collaborative knowledge management platform that allows organizations to store and manage a wide range of digital objects—from simple and compound documents, data records, molecular models, image and video files, to search queries and URLs—and provides controlled user access to these objects. All of the electronic records maintained by Life Sciences companies can be stored and managed in Content Suite.

Benefits of a Quality Document Management System:

- Remove paper and automate manual review and approval processes. This reduces opportunities for errors in data entry and routing of paper forms.
- Find all quality information in one location, quickly and easily. With all information easily accessible via a web browser – not sitting in binders or a file cabinet – you can quickly access any quality information from anywhere in the organization.
- Ensure compliance with internal and external regulations. By automating your quality systems, you are assured information gets to the right person at the right time and acted upon within the specified time requirement, thus reducing incidents of non-compliance.
- Have detailed reports, version control on all documents, and audit trails for any activity to prove compliance at any point in the quality process.

Content Lifecycle Management

Content Suite provides the ability to perform lifecycle management of all electronic content including Microsoft® Office files, XML files, emails, PDFs, CADs, multi-media, UTF-8 content, etc. This content is stored in the ECM repository, tracked, retained for its lifecycle and disposed of once the end of life is reached for that content. The electronic content can have metadata (data elements) associated with the content providing information about the content. For instance, is the content a Microsoft Word document or an email or an HR record, or an official record of the corporation, or an SOP document? Each of these items has a different lifespan and can be involved in very different business processes during their lifecycles. The access permissions on each of these items vary significantly as well. The ability to classify electronic content, control its access, manage it with defined processes (workflows), retain it for the appropriate length of time and then dispose of it in a legally defensible manner is a cornerstone of the content lifecycle management (CLM) solution. But CLM is not just about controlling and managing business content and the repositories where it resides. It is about understanding the relationship between people, processes and content in a corporation. It is also about documenting how content flows within and across departments, what systems it touches and what processes with which it is associated.

Content can be created from a variety of sources. All forms of data content can be managed as users typically work via their desktops in user-friendly applications such as Microsoft Office or Outlook

or IBM® Notes®. By logging into the Content Suite through their preferred browser (Internet Explorer, Firefox, Safari), users can download, upload and edit content within the repository, with all content controlled by access permissions.

Search

As content is received by Content Suite, it is indexed, associated with any default metadata (categories) and stored in a repository location as specified by the user. Access permissions are also set according to the administrator-configured parameters and the location chosen. It is then exposed to a rich search engine that can perform searches against both the content data and the contents of the metadata using simple and complex full-text and Boolean search strings. The domain of the search can be limited to just a portion of the repository or it can span the entire repository. Through the use of federated searches, the search can be expanded to include file systems and other repositories. A search query can return exact matches or similar matches including "sounds like" search criteria. The results of both the search and the search template can be stored, as desired by the user. Additional searches refining the search template are also available. As with all content stored in the repository, access permissions control what content is returned as a result of a search. If a user does not have permission to see that specific content exists, it will not be shown in the search results. Content is also exposed to a powerful business process engine (workflows) that allow organizations to route documents through the various stages in the documents lifecycle. Approval, review, edits and comments are all possible steps along the workflow process.

Audit and Version Control

As changes occur to content (new versions, edits, deletions) all actions are logged in an audit trail so accountability of all content is maintained across the repository. The system administrator can review this audit log as desired.

When an additional version of the same content is stored in the repository, a newer version is added and becomes the default version when the content is searched, opened for viewing or opened for editing. However, previous versions, back to a configured maximum number of versions, are still available for comparisons or as a backup to be reverted if necessary. While content is stored in folders in the repository, users can create shortcuts from their personal repository workspaces to their favorite content or folders for faster access.

Notifications

When content is added to Content Suite, notifications can be sent out automatically as desired by users. For instance, a user can choose to be notified by email whenever a new item or version is added to a specific folder. They can choose to receive such a notification immediately, hourly or daily. As workflows process corporate data, users are always notified via an assignment list, and can also be notified via email, when a workflow step requires their participation. This notification can be a review, approval, electronic signature or just informing them that a specific action is needed. A deadline can be imposed and when the user exceeds that deadline, escalations can occur as well. The administrator can review the system-wide list of assignments and tasks and outstanding items are clearly flagged for review. The administrator can re-assign any task if, for instance, a user is out on holiday or otherwise unavailable.

Archiving

Content can be added to the repository through local and remote user action, bulk loading utilities or connectors that draw content from other repositories. Content can be kept on file storage or moved to the OpenText Archive Server which performs single-instance archiving, compression and encryption as desired. Storage via the Archive Server can be on disk or worm or optical media or magnetic tape. Content stored within the Archive Server is managed and accessed like all other repository content.

Software Validation

The Quality Document Management solution has been extensively validated using GAMP 4 and GAMP 5 principles for quality system regulations (QSR) (21 CFR Part 820) and electronic records rules (21 CFR Part 11) at many firms by OpenText, partners, system integrators, and/or in-house staff. Because the software is primarily configured rather than customized with code, upgrades and software re-validation are less resource-intensive.

Extended Third Party Solutions

While the Quality Document Management solution could serve as the document management infrastructure for many Life Sciences processes, it was designed with Quality Systems in mind. In areas such as Quality Assurance, Clinical Trial Management, Regulatory Affairs, and Manufacturing and Distribution, OpenText has partnered with leading companies, such as US Data Management, Global Cents, Quintiles, and KineMatik, to offer OpenText Content Suite-based solutions employing best practices and complying with standards such as GxP and GAMP. Additionally, with over 100 RESTful APIs, OpenText Content Suite allows smooth integration with your existing QMS applications and has been integrated with several industry-leading Quality Management Systems solutions at dozens of customers.

Summary

Coordinating and streamlining quality programs across the enterprise, while maintaining regulatory compliance, are primary among the challenges that Life Sciences organizations face today. The opportunity to cut costs and reduce dependency on paper processes is of enormous benefit. In the life sciences industry, one of the key factors in maintaining regulatory compliance is the management and control of key documents that are subject to various regulations. All aspects of a quality system generate regulated documents such as policies, standard operating procedures (SOPs), work instructions, investigation reports, audit reports, training reports and validation documentation.

Our Quality Document Management solution enables your organization to manage and control regulated documents throughout their lifecycles. Documents that are needed for audits, CAPA, training and so on can be created, reviewed, approved, edited and maintained within the Quality Management repository. This functionality can be built into the workflows for both audits and CAPA. Regulated documents are maintained in full compliance with the FDA's 21 CFR Part 11, including the ability to render and electronically sign approved documents. Thus, the Quality Document Management solution offers companies the software infrastructure to remain compliant, reduce costs of records management, and establish best practice through collaboration.