OPENTEXT REGULATED DOCUMENTS

Manage and control regulated documents throughout their lifecycle while accelerating time-to-market and reducing total cost of ownership

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Product overview

The life sciences industry is subject to strict regulations that dictate how, when, and under what circumstances electronic documents can be authored, updated, approved, published, archived, and destroyed. In the race to market, regulated industries need to make regulatory compliance an integral part of their document management and control processes to reduce risk, gain competitive advantage and bring new products to market faster. Achieving compliance is not just a business issue for the life sciences industry as several other regulated industry sectors, such as financial services and government agencies, are also facing similar challenges.

BENEFITS

Industry Compliance:

A comprehensive system for controlled documents ensures compliance with 21 CFR Part 11 and reduces regulatory risk.

Enterprise Content Management (ECM) platform:

A full-featured, industry-leading, highly scalable, web-based document management platform provides a single repository for securely organizing, controlling, and sharing enterprise content.

Configurable Workflow:

A configuration-based solution reduces the initial validation effort and eliminates the need for additional re-validation when workflows change greatly reducing time to market and total cost of ownership.

Ease of Use:

Design workflows graphically with drag and drop icons. Access regulated content and review and approval steps via familiar desktop applications such as Microsoft® Office and SAP®

BENEFITS

Records Management:

Enable compliant lifecycle management of all enterprise content, by proactively enforcing corporate and regulatory policies and procedures without impacting the way users work. Streamline records retention and destruction processes.

Controlled Viewing and Printing:

Simplify compliance enforcement through efficient configuration of viewing and printing rules and leveraging records management classifications. Only allow viewing and printing of approved and effective SOP's and other controlled documents.

Regulated document management

OpenText Regulated Documents is a complete out-of-the-box solution that enables organizations in highly regulated industries to manage and control key documents throughout their lifecycle. By providing a consistent process for managing documents, Regulated Documents ensures compliance with various regulations, including the U.S. 21 CFR Part 11.

Regulated Documents is designed to carefully manage controlled documents through a controlled lifecycle that includes document authoring, reviews, approvals, dissemination, and disposition. The system will support as many unique document lifecycles as needed by the enterprise, and these lifecycles are implemented and updated without the need for customized code, greatly reducing validation time and expense.

To provide a complete solution, OpenText offers premium services for Regulated Documents to guide you through the installation and validation processes, and provides you with the training and support needed to deploy the solution rapidly.

Manage Standard Operating Procedures (SOPs)

With Regulated Documents, you can carefully manage and control business-critical documents, such as SOPs, from creation through to final destruction.

Since SOPs pass through a series of stages where multiple users or groups must review and approve the document before it is disseminated, Regulated Documents has electronic signature capability, where approvers electronically sign a document to indicate that it is approved for release. Prior to release, appropriate effective dates and a records management plan are assigned to the document, ensuring the document is accurately maintained and retired based on records management policies.

Ensure document security

Regulated Documents provides a number of features to ensure that the repository is secure, that only authorized users can electronically sign approvals of documents, and that documents cannot be tampered with after approval.

Browse and retrieve documents

Productivity suffers when users struggle to find documents, verify latest versions, and put context around content created by other people. Regulated Documents provides several methods for browsing documents, including navigating folders or navigating taxonomy hierarchies in the web interface among others. The powerful search feature of Regulated Documents allows users to quickly find and retrieve documents that they need, when they need them, including full text and attribute/ metadata searches.

Author documents

Because the document lifecycle begins with a request to create a new document, Regulated Documents streamlines the document authoring process using templates, workflows, and unique document numbering. Regulated Documents allows authors to manually assign reviewers and approvers or to have them automatically assigned based on business rules. After the content has been created, the document author initiates a workflow for review and approval which automatically adds the document to an "In Progress" folder.

Review documents

Using workflows and tasks, Regulated Documents helps you effectively manage the review and modification of documents with features like automatic email notifications to reviewers. Reviewers can quickly review and comment on the document by clicking on links within the email or accessing the application via the web. After a new version of the document has been created, the system notifies the users that the document is ready for approval, sets the document status to "Reviewed" and posts the document in a "Reviewed" folder.

Approve documents

Using workflows and electronic signatures, Regulated Documents ensures that only documents that meet organizational guidelines, policies and procedures are approved. Document approvers can review the document and choose to approve and sign off on it or reject the content, simply by clicking on links within an email notification or by accessing the application via the web. Once all approvals are obtained, all approvers' electronic signatures are added to a nonmodifiable rendition of the document and the author sets the status of the document to "Approved" and adds the effective date of the approval to the document's attributes.

Deploy documents with compliant controls

OpenText Regulated Documents enables organizations to deliver complete, comprehensive record classification and lifecycle management for all corporate records and information holdings, regardless of content store or format (paper or electronic). It empowers information workers to capture and categorize the corporate content they manage according to organizational policies, thereby ensuring regulatory compliance, reducing risk, streamlining auditability and transparency, and increasing the efficiency and cost effectiveness of necessary tasks.

OpenText Regulated Documents

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The workflow and records management capabilities of Regulated Documents help you classify and secure documents prior to deployment. In a Controlled Document environment, the approved document is given a records management classification, such as "Policy," and the status of the document is set to "Released." Documents can then be watermarked, secured and placed in the appropriate folder hierarchy.

Document printing and viewing can be controlled using rules configured to stamp, watermark, and/or add a cover page so that multiple users can print or view the same document in different ways. The solution provides industry-compliant functionality for controlling hardcopies of regulated documents and for distinguishing official copies by adding certain information to the copies created from viewed contents.

FOR EXAMPLE:

Official Copies:

Users can access controlled documents by requesting an official controlled copy, which is the method used when they need to track controlled copies of those documents. The controlled official copies can include information indicating who requested and received the controlled copy, when this controlled copy was requested and provided to the user.

Working Copies:

When a user accesses a controlled document, without using the official "Request controlled Official Copy" functionality, the user receives a stamped and watermarked version of the document showing that the document is a working copy and identifying who accessed the document.

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Control, monitor, and simplify the disposition process

The Regulated Documents records management capabilities control the archival and final disposition of documents. Powerful disposition automation, reporting, and searching provide enhanced control and awareness surrounding the disposition process. Records Managers can leverage the following capabilities available in the product to configure the system to achieve records management compliance:

Automated disposition: Automate the disposition of records according to organizational requirements.

Detailed disposition reporting: Create full and detailed listings of records that are ready for review or final disposition, and route listings to appropriate individuals for review and approval.

Disposition searching: Perform disposition searching against items. Searching calculates the disposition date of the items based on the Record Series Identifiers (RSI) schedule, and returns the records ready for deletion, archiving, or moving on to the next stage in their lifecycle.
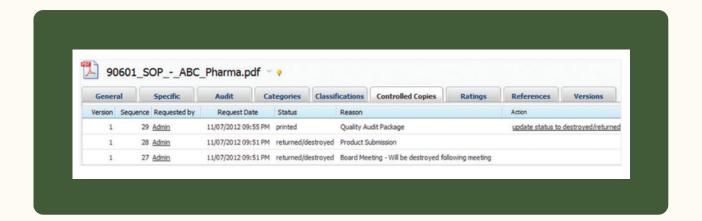
Ensure compliance, reduce time-to-market

Regulated Documents gives organizations the right mix of industry-leading ECM tools to manage content throughout its entire lifecycle and orchestrate people, process, and content to create business value and achieve strategic success.

This integrated offering helps increase productivity through imaging, document management, graphical and intuitive workflow, electronic signature, and controlled viewing and printing, minimizing the risks and costs associated with content through its top ranked records management and archiving capabilities.

By making the management and control of key documents in heavily regulated industries more efficient and compliant with relevant regulations, Regulated Documents reduces the risk associated with non-compliance and accelerates time-to-market to enhance competitive advantage.n

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General	Specific	Audit	Categories	Classifications	Controlled Copies	Ratings	References	Versions

Version	Sequence	Requested by	Request Date	Status	Reason	Action
1	29	Admin	11/07/2012 09:55 PM	printed	Quality Audit Package	update status to destroyed/returned
1	28	Admin	11/07/2012 09:51 PM	returned/destroyed	Product Submission	
1	27	Admin	11/07/2012 09:51 PM	returned/destroyed	Board Meeting - Will be destroyed following meeting	

ABOUT ISEOSOLUTIONS

We specialize in Enterprise Information Management solutions for collaboration, document management, archiving and the optimization of document-centric business processes from the first idea to the replacement / migration of an application.

We focus on customers and prospects in Switzerland and abroad targeting small, medium and large companies with SAP®, OpenText® and Microsoft® as strategic IT suppliers.

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