# Livelink ECM – Regulated Documents

## Enable your organization to manage and control key documents throughout their entire lifecycle

Many industry sectors such as pharmaceuticals, life sciences, financial services, and government agencies are subject to strict regulations that dictate how, when, and under what circumstances electronic documents can be authored, updated, approved, published, and archived. In the race to market, regulated industries need to make compliance with regulations an integral part of their document management and control processes to reduce risk and gain competitive advantage by bringing new products to market faster.

### Regulated document management

Designed to meet the strict requirements of the pharmaceutical industry, Livelink ECM – Regulated Documents is a complete solution that enables your organization to manage and control key documents throughout their entire lifecycle. By providing a consistent process for managing documents, Regulated Documents ensures compliance with various regulations, including the U.S. Food and Drug Administration's (FDA's) 21 CFR Part 11.


Regulated Documents is designed to carefully manage critical documents through a controlled lifecycle that includes document authoring, reviews, approvals, and dissemination. To provide a complete solution, Open Text 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.

### Standardize documents

With Regulated Documents, you can publish standardized document templates, simplifying the document creation and modification process for your employees while adhering to established organizational guidelines. In a Controlled Document Environment, users submit a formalized workflow request to create a new document or modify an existing one. Based on the request, the appropriate template is sent to the requesting user, who can easily create and modify information before passing the document on for review. In a Managed Document Environment, users browse through a set of templates and choose the one that best meets their requirements. For both types of environments, Regulated Documents provides users with a set of documents that describes the list of steps and guidelines that must be followed in each phase of the document lifecycle.

### Manage SOPs

Standard Operating Procedures (SOPs) are a key part of your many business processes. With Regulated Documents, you can carefully manage and control business-critical documents, such as SOPs, from creation through to final destruction. SOPs pass through a series of stages where multiple users or groups must review and approve the document before it is disseminated. Using Regulated Documents' electronic signature capability, 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. Regulated Documents integrates with directory service applications to support centralized management of user and group directories and to provide single login. Documents and folders have nine levels of permissions to ensure that only authorized users can access, view, edit, or delete documents.

Regulated Documents further ensures security by automatically logging users out if their terminal is inactive for a period of time and by locking users out if they have too many unsuccessful login attempts. To ensure that only authorized users sign documents, approvers are challenged for their password each time that they apply their electronic signature.

### Browse and retrieve documents

Regulated Documents provides several methods for browsing documents, including navigating folders or navigating taxonomic classification hierarchies in the Web interface, or by navigating folders via Microsoft Windows Explorer. Regulated Documents' powerful search features allow users to quickly find and retrieve relevant documents.

## Author documents

The document lifecycle begins with a request to create a new document. Regulated Documents helps you streamline the document authoring process using templates, workflows, and unique document numbers. In a Controlled Document Environment, users request permission from the document control group to create a new document. If the request is approved, the appropriate document template is sent to the requesting user, a draft status is applied, and a unique document ID is generated. After the content has been created, the document author initiates a workflow for the document control group to add the document to the *IN PROGRESS* folder.

Using Regulated Documents' desktop integration features, document authors can connect directly from Microsoft® Word to the Regulated Documents repository to save new documents or to check-out existing documents for which there has been a change request.

## Review documents

Using workflows and tasks, Regulated Documents helps you effectively manage the review and modification of documents. In a Controlled Document Environment, a document author initiates a document review workflow that shows up as a task in the reviewers' assignments.

Document reviewers can collaboratively make modifications in parallel to the document and send their suggestions to the author. Document reviews by multiple reviewers are performed collaboratively using Regulated Documents' Review Manager for Acrobat feature, which allows multiple reviewers to add their comments concurrently as layers of the document being reviewed.

Once reviews have been returned, the document author can consolidate reviewers' suggestions to create a new version of the document. After a new version of the document incorporating reviewers' comments has been created, the document author notifies the document control group that the document is ready for approval. The document control group sets the document status to *reviewed* and posts the document in the *REVIEWED* folder.

## Approve documents

Using workflows and electronic signatures, Regulated Documents ensures that only documents that meet organizational guidelines, policies and procedures are approved. In a Controlled Document Environment, the document author initiates a document approval workflow that shows up as a task in the approvers' assignments. Document approvers review the document and choose to approve and sign off on it, or reject the content.

The Approving parties' electronic signatures are added to a non-modifiable rendition of the document. Once all approvals are obtained, 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

Regulated Documents' workflow and records management capabilities 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*. The document is then watermarked, secured and placed in the *RELEASED* folder.

## Archive documents

The document lifecycle ends with the withdrawal and eventual purge of documents from the repository. Regulated Documents' records management capabilities help you control the archive and final disposition of documents. Records managers issue a query to locate all inactive controlled documents in the repository, set the status to *archive*, and then move the selected documents to the *ARCHIVE* folder.

## Ensure compliance, reduce time-to-market

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.

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