

PRODUCT OVERVIEW

OpenText™ Documentum for Submission Store and View

Obtain a 360-degree view of regulatory activity and improve compliance of archived submissions



Securely store submissions and correspondence



Quickly respond to health authorities



Easily find correspondence linked to submissions




Cloud-native software runs anywhere

Efficient access to archived regulatory submissions, along with their associated correspondence, is a common challenge for life sciences companies. OpenText Documentum Submission Store and View, part of OpenText Documentum for Life Sciences, simplifies the search and retrieval of archived submissions and their associated correspondence, while improving security and compliance. The solution links regulatory correspondence and communications to submission files, enabling a full view of regulatory activity.

Access submissions and correspondence in one place

Many life sciences organizations use publishing tools to submit their regulatory submissions; these tools then store the submissions on file shares. Agency query and response documents, meeting materials, and telephone conversation records are usually saved in emails, on personal PCs, or various collaboration tools.

Responding to inquiries or keeping track of communications between the sponsor and agency can quickly spiral into a complex mess: hours wasted searching multiple systems, duplicating effort, or simply trying to guess where the right information exists. And at times, quickly finding and accessing regulatory correspondence can be just as important as locating the submission itself.

 **OpenText Documentum Submission Store and View**

List of associated OpenText products the component works with

- **OpenText™ Documentum™ for Life Sciences**
- **OpenText™ Life Sciences Smart View**
- **OpenText™ Documentum™ for Research and Development**
- **OpenText™ Documentum™ for Quality and Manufacturing**
- **OpenText™ Documentum™ for eTMF**
- **OpenText™ Documentum™**
- **OpenText™ Documentum™ D2**

With Documentum Submission Store and View, you can easily retrieve the regulatory correspondence associated with drug products or submissions, giving you a 360-degree view of regulatory activity. Storing and linking correspondence and associated communications with submissions in a central secure repository enables effective alignment with your Global Dossier, and ensures more efficient and transparent tracking of open/closed queries.

Unmatched compliance and security

Move submission files off uncontrolled file shares into a secure, compliant Documentum repository. Audit trails and indexing provide more efficient tracking of submissions and queries, and enables a complete view to provide clarity and a better understanding with regulatory agencies. Auto-matically store regulatory submissions while retaining deep folder structures exactly as they were submitted to the regulatory agency.

Streamlined eCTD viewing

View and navigate the eCTD table of contents (XML backbone) within Documentum and view imported NeeS or paper submissions by navigating the standard cabinet-folder hierarchy. Supports any global format of the eCTD, including the US, EU, and Japan. New regions and new versions of the standard, including eCTD4, can be easily supported without upgrading the solution version.

Should a change affect multiple submissions, Documentum Submission Store and View supports Grouped Variations/Submissions and automatically queries against all affected products and/or manufacturers to suggest potential affected applications that should be included in a regulatory activity package.

Delivered with cloud-native technologies

By leveraging state-of-the-art technology from Docker and Kubernetes, Documentum Submission Store and View can be efficiently deployed on-premises and in any cloud providing streamlined deployment, management, and upgrades. These new technologies have come together to make it easier than ever to upgrade Documentum to the latest version and take advantage of new features, capabilities and updates.

Feature	Description
Controlled compliance	Store regulatory submissions and associated communications in a compliant and secure repository. Set access controls, password strength, and log-in attempts to strengthen your compliance.
Easy import	Add legacy and current submissions in eCTD, NeeS, or paper format. Automatically assign submission properties, document types, and security levels to ensure accuracy. Maintains all eCTD navigation, inter-document hyperlinks embedded in PDF files, and encryption.
Respond quickly to health authorities	Search for archived submissions based on metadata properties, such as product, country, submission type, manufacturer, or date. Automatically query and suggest applications to include during instances of Grouped Variations/Submissions.
Integrates with Microsoft® Outlook®	Drag and drop emails and their attachments directly into the repository for automatic import
Streamline viewing	Provides standard eCTD views—single, current, and cumulative—of the full regulatory submission lifecycle, including navigation of hyperlinks