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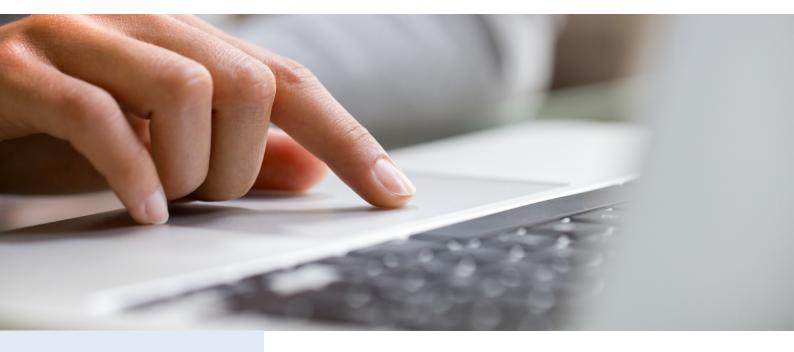
OpenText Documentum Submission Store and View

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

Ⓢ Store regulatory submissions and associated communications in a compliant and secure repository

👁 Easily access and view regulatory correspondence linked with submissions

🔍 Quickly search and retrieve archived submissions and associated documents

🎯 Automatically query and suggest applications to include during instances of Grouped Variations/Submissions

Are you having a hard time finding and keeping track of your organization's growing volume of electronic submissions and regulatory correspondence? You are not alone. Efficient access to archived submissions, along with their associated correspondence, has become a challenge with which almost every life sciences firm grapples.

A complete view of regulatory activity

OpenText Documentum Submission Store and View, part of the 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

Today, many life sciences organizations are using publishing tools to submit their regulatory submissions and store them on file shares. On the other hand, agency query and response documents, meeting materials, and telephone conversation records are usually saved in emails, on personals PCs or in various collaboration tools.

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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. At times, quickly finding and accessing regulatory correspondence can be just as important as locating the submission itself.

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. The solution delivers the ability to:

- Integrate with Microsoft® Outlook®, allowing users to drag and drop emails and their attachments directly into the repository for automatic import.

- Use an established document taxonomy for submissions and correspondence.

- Associate source documentation and correspondence at the application or submission level.

- Support Grouped Variations/Submissions with automatic queries.

Unmatched compliance and security

Documentum Submission Store and View enable you to 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. Additionally, the ability to set access controls, password strength and log-in attempts further strengthen your compliance.

With Documentum Submission Store and View, you can automatically store regulatory submissions while retaining deep folder structures exactly as they were submitted to the regulatory agency. Other key capabilities of the solution include:

- Importing and storing legacy and current submissions in eCTD, NeeS, or paper format.

- Maintaining all eCTD navigation and inter-document hyperlinks embedded in PDF files, as well as encryption.

- Auto-assigning submission properties, document types, and security levels.

Additionally, you can easily search for archived submissions based on metadata properties, such as product, country, submission type, manufacturer or date.

Streamlined eCTD viewing

Documentum Submission Store and View provides standard eCTD views—Single, Current, and Cumulative—of the full regulatory submission lifecycle, including navigation of hyperlinks. You can 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. Addition- ally, Documentum Submission Store and View supports any global format of the eCTD, including the United States, European Union, and Japan. New regions and new versions of the standard, including eCTD4, can be easily supported without upgrading the solution version.

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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.

Get started today

Get started today with a submission storage and viewing solution built on OpenText Documentum, the industry's most trusted content management platform.

About OpenText

OpenText, The Information Company, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) visit opentext.com.

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