

EMC DOCUMENTUM SUBMISSION STORE AND VIEW

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

ESSENTIALS

- Store regulatory submissions and associated communications in a compliant and secure repository
- Import submissions in eCTD, NeeS or paper formats
- Easily access and view regulatory correspondence linked with submissions
- Quickly search and retrieve archived submissions and associated documents
- Streamline Electronic Common Technical Document (eCTD) viewing
- Automatically query and suggest applications to include during instances of Grouped Variations / Submissions

A COMPLETE VIEW OF REGULATORY ACTIVITY

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

EMC® Documentum® Submission Store and View (Documentum SSV), part of the EMC Documentum for Life Sciences solution suite, 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; these tools then store the submissions on file shares. On the other hand, 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.

With Documentum SSV, 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 secure repository better aligns with your Global Dossier, and ensures more efficient 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
- Utilize an established document taxonomy for submissions and correspondence
- Associate source documentation and correspondence at the submission level
- Support Grouped Variations / Submissions with automatic queries

UNMATCHED COMPLIANCE AND SECURITY

Documentum Submission Store and View enables 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 login attempts, further strengthens your compliance.

REDEFINE

SOLUTION OVERVIEW

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With Documentum SSV 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 SSV 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. Additionally, Documentum SSV 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 impact multiple submissions, Documentum SSV 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 EMC Documentum, the industry's most trusted content management platform. For more information about EMC Documentum Submission Store and View, please visit us at www.emc.com/documentumforlifesciences.

CONTACT US

To learn more about how EMC products, services, and solutions can help solve your business and IT challenges, [contact](#) your local representative or authorized reseller, visit www.emc.com, or explore and compare products in the [EMC Store](#).

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