



EMC Documentum Regulatory Submissions Solution for Life Sciences

Enabling electronic submissions to speed NDA approvals and time to market

The Big Picture

- Streamline the review and approval process for new products, reduce the cost and complexity of regulatory submissions, and accelerate global time to approval and time to market
- Enable collaboration as work teams to plan, create, edit, and generate drafts that are managed in a central repository for review, approval, and publishing
- Gain efficiencies by making information quickly accessible and easily reusable for new submissions
- Allow regulatory bodies anywhere in the world to review documents simultaneously
- Consolidate multiple archive technologies and processes into a comprehensive, centrally-managed workflow for electronic submissions
- Automate compliance to reduce the risk of legal penalties and achieve lower costs of legal discovery, research, and prosecution

Business challenge

With a typical new drug application (NDA) submission incorporating over one million pages of content, including summary and clinical study reports, life sciences companies often experience lengthy approval delays as they bring new therapeutics to market. Today, a submissions preparation often involves a manual, paper-based process to multiple regulatory bodies, each requiring different information. Every day a submittal is delayed can result in a loss of \$1-3 million in sales revenue, depending on the drug. This labor-intensive, paper-based submission process rarely offers capabilities to incorporate or track changes, serialize workflow, or provide a feedback loop to the original content author.

The Electronic Common Technical Document (eCTD) offers life sciences companies the opportunity to transform and automate their submission process by providing a standard format for the United States, European, and Japanese regulatory agencies. The goal of this common format for submission documentation is to significantly reduce the time and resources needed to assemble NDAs for the registration of human pharmaceuticals. At the same time, life sciences companies also need to address other initiatives and standards including Secure Access for Everyone (SAFE), Clinical Data Interchange Standardization Labeling (CDISC), Product Information Management (PIM), and Structured Product Labeling (SPL).

Solution overview

The EMC[®] Documentum[®] integrated platform for regulatory submissions enables life sciences organizations to build an infrastructure for creating and assembling electronic submissions while meeting compliance requirements. Submissions can be made electronically in conformance with the eCTD standard or, through integration with EMC technology partners and systems integrators, in physical paper format. All content that is relevant to a submission can be tracked and managed—including unstructured and structured content for clinical trials information, drug chemical makeup, manufacturing processes, scientific rationale, preclinical testing reports, human clinical testing results, and proposed product labeling.

EMC's unique combination of content management and archiving software, tiered-network storage, and services helps life sciences organizations comply with the integrity, confidentiality, and accessibility requirements of eCTD initiatives—while lowering the total cost of managing mission-critical submissions information.

Solution components

Components of the comprehensive EMC Documentum regulatory submissions solution include:

- EMC Documentum 5.3 Platform—enterprise content management platform for creating, capturing, managing, delivering, and publishing large volumes of content within and beyond the life sciences enterprise.
- EMC Documentum Authoring Integration Services 5.3—provides support for Adobe Acrobat integration for PDF manipulation and auditing.
- EMC Documentum Trusted Content Services 5.3—for electronic signatures and compliance with authentication schemes such as the SAFE initiative.
- EMC Documentum Regulatory Publishing Transformation Services 5.3—automatically renders submissions documents to support enhanced PDF and XML operations, including PDF assembly, bookmarks, hyperlinks, and watermarks.
- EMC Documentum Submissions Manager 5.3 for eCTD—extends Documentum Webtop to provide functionality used specifically for creating and publishing electronic submissions.

Additional platform components may include the following EMC Documentum products: Compliance Manager, Web Publisher, Records Manager, Business Process Manager, Content Storage Services, and Enterprise Content Integration Services.

Take the Next Step

Support your regulatory submissions software environment with the highest-performing, tiered-network storage platforms and storage management software from EMC, including services that help you define storage tiers and data policy, align applications, increase utilization, and improve storage operations.

To learn about how the EMC Documentum solution for regulatory submissions can make your company's submission process far faster and more efficient, visit www.EMC.com/lifesciences or <http://software.EMC.com>; or call **800.607.9546** (outside the U.S.: +1.925.600.5802).



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