

EMC[®] DOCUMENTUM[®] RESEARCH AND DEVELOPMENT

Accelerate the creation, review and approval of regulatory submission documentation

ESSENTIALS

- Ensure submission-ready documentation with all required content elements included
- Streamline review and approval processes using collaborative authoring for simultaneous review, editing and approval
- Boost productivity using a template-based authoring process, support for virtual documents and an easy to use interface
- Enable mobile workers to participate in review and approval workflows while on the go
- Link content across solutions for consistent, simplified document management and user access
- Support the Tech Transfer process by ensuring document traceability between regulatory and quality
- Reduce risk with a proactive, automated expiry review process
- Demonstrate compliance through extensive audit trails, access control, lifecycle management and version control
- Leverage a proven, trusted, scalable platform that's available on premise or in the cloud

IS YOUR PROCESS FOR CREATING SUBMISSION READY DOCUMENTATION EFFICIENT?

Streamlining the regulatory submission process is essential to getting products to market faster today. But you need to create, review and maintain essential submission-related documentation appropriately, even as regulatory rules and requirements vary and evolve by country and region.

By automating this process using EMC Documentum Research and Development (Documentum R&D), you can efficiently manage the creation, review and approval of regulatory submission documentation globally. You'll not only accelerate the submission process, but also benefit from uncompromised compliance, complete global control of content and secure information sharing across the extended enterprise.

A COMPLETE SOLUTION FOR MANAGING REGULATORY SUBMISSION DOCUMENTATION

Part of the EMC Documentum for Life Sciences solution suite and available on premise or in the cloud, the solution enables organizations to create, review and approve regulatory submission documentation more efficiently. Predefined taxonomies, workflows and templates reduce deployment time and ensure adherence to industry standards, while collaborative authoring capabilities and automated workflows improve productivity and streamline review and approval processes. Intuitive, role-based interfaces boost user adoption and reduce training costs. And with the ability to link and share content across EMC's solution suite, it's never been easier to quickly search, identify and retrieve submission-ready content.

Key capabilities include:

- Configurable, role-based views
- Predefined document inventories and registration forms
- Automated metadata tagging and metadata based security models
- Automatic virtual document creation based on controlled templates
- Pre-built, granular and flexible workflows including automated expiry review
- Collaborative authoring and review process for simultaneous editing
- Faceted search to make it easy to find and view content
- Traceability and notifications between regulatory and quality documentation

IMPROVE SUBMISSION ACCURACY

Documentum R&D helps eliminate data entry activities and improve the accuracy of your submissions. To achieve this, it leverages the industry- standard dictionaries, taxonomies and object models of the Drug Information Association (DIA) Electronic Document Management (EDM) reference model. The solution also provides predefined, reusable registration forms and preconfigured document inventories based on industry standards and regulatory guidance. Documentum R&D also facilitates authoring compliance in accordance with International Committee on Harmonization Common Technical Document (ICH CTD) formats.

REDEFINE

SOLUTION OVERVIEW

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BOOST AUTHOR PRODUCTIVITY AND COLLABORATION

Authors can select from a predefined inventory of reusable, industry-standard documents that are automatically linked with the associated document types required for submissions. Also, virtual documents can be automatically created from controlled templates. This ensures that people always work from the current, most up-to-date templates.

Streamline the review and approval process with collaborative editing. Multiple contributors can view a consolidated copy of all previous edits and then simultaneously make their own changes using the standard “track changes” functionality of Microsoft Word. The solution automatically merges all edits into a single document and allows the designated primary author to accept, reject and review changes on a rolling basis. When a document is ready to be finalized, the solution supports a single, streamlined workflow for all contributors to do final review (rather than multiple, serial workflows).

Finally, mobile integration and synchronization enables Documentum R&D to automatically push controlled documents to mobile devices to help keep things moving.

SPEED SEARCH AND RETRIEVAL OF DOCUMENTATION

With Documentum R&D, users can quickly identify submission-related documentation using faceted navigation, based on ICH CTD standards, that identifies and classifies documents using industry dictionaries and metadata. When a category is selected, the solution automatically reduces the document list to reflect only relevant documents.

Further, all solutions in the EMC Documentum for Life Sciences solution suite interoperate allowing content to be linked across solutions to eliminate manual workarounds, simplify access and provide an authoritative source for content.

AVAILABLE ON-PREMISE OR IN THE CLOUD

EMC gives you choice and flexibility when deploying Documentum R&D to meet your unique combination of access, security and privacy needs. Documentum R&D is available on premise or in the cloud so you can decide how to best align with your security, budget and IT administration requirements.

With EMC OnDemand, you can leverage a managed service to reduce demands on your internal IT staff while reducing total cost of ownership by 30%-60%. If easy, browser-based access is paramount, a public cloud solution provides the ubiquitous access needed in a single tenant application. And as always, you can choose a traditional on premise deployment that gives you full control. Regardless of your choice, EMC offers enterprise-grade, best-in-class security, backup and recovery options from VMware, RSA and EMC so you can deploy Documentum R&D with confidence.

MINIMIZE COMPLIANCE RISK

Documentum R&D reduces noncompliance risk by automating and enforcing appropriate approval processes. It automatically assigns review and approval workflows based on predefined, business rules and then routes documents for review and approvals to the appropriate people based on document type.

Equally important, the solution helps you clearly demonstrate regulatory compliance such as 21 CFR Part 11 compliance by creating detailed audit trails with e- approvals and e-signatures. And dynamic security and access controls ensure that only the right people access the right documents at the right time.

GET STARTED TODAY

Accelerate the creation, review and approval of regulatory submission documentation with EMC Documentum. To learn more, visit us at www.emc.com.

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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