Regulatory Document Management for Life Sciences

Creating and managing regulatory submissions becomes more challenging every year. The size of NDAs continues to expand, with some containing more than 500,000 pages of documents and data. And, the sheer volume of submissions is increasing. Managing the amendments, supplements, and variations required to maintain and expand the product portfolio creates massive complexity and cost.

Aurea Compliance Manager (ACM) Regulatory Document Management delivers a pre-configured, user-friendly solution for managing submission documentation, while minimizing the demands on already overtaxed business and IT users.

ACM FEATURES:

- Configurable content transformation and lifecycle management
- Complete inventory of Nonclinical, Clinical, Quality, and Regulatory/ Administrative documents
- Built on EDM Reference Model specifications
- Available in the Cloud for speed and flexibility

The best in document management with regulatory expertise at the core

ACM Regulatory Document Management delivers Life Sciences industry expertise alongside best-of-breed document management. Designed to help you avoid the high cost of ownership associated with custom solutions, Regulatory Document Management starts with our industry proven configuration, while also providing fast and easy configuration tools to tailor every process to your business.

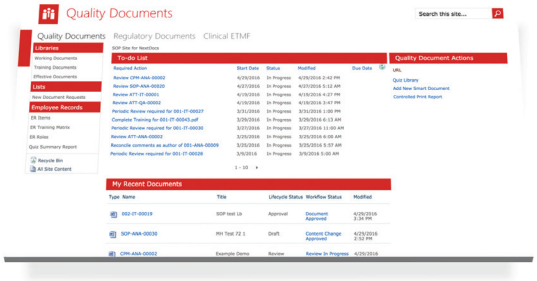
KEY ACM REGULATORY DOCUMENT MANAGEMENT BENEFITS:

Built for submissions: RDM simplifies adherence to industry best-practice by taking advantage of a preconfigured EDM Reference Model. The EDM Reference Model is a taxonomy/metadata reference model developed by Life Sciences industry experts that incorporates lessons learned from across the industry, and maps extensively to regulatory requirements.

Automated production of submission-ready documents: RDM guides users through the production of submission-ready documents by enforcing the use of CTD-required granularity, applying necessary templates, and producing PDF renditions that meet complex agency requirements. RDM also enables the collection of industry compliant electronic signatures.

Scalable for the enterprise: RDM is proven to handle massive document volumes over local and wide area networks, providing users with the performance they expect.

Aurea Compliance Manager across the Life Sciences lifecycle



Regulatory Document Management is part of the comprehensive Aurea Compliance Manager (ACM) suite. Aurea Compliance Manager delivers end-to-end integrated solutions designed to address the specific workflow, compliance, and regulatory needs in the Life Sciences.

Electronic Trial Master File: Simplify, streamline, and automate clinical trial processes and clinical document management with ACM Electronic Trial Master File (eTMF).

Trial Exchange: Create speed, efficiency, and ease for investigators and site staff to communicate, collaborate, and submit/review documents through this simple clinical portal for trial site staff.

SOP & Training: Deploy effective and compliant SOP & Training processes throughout the entire policy and procedure lifecycle.

Quality Management Solutions: ACM offers a suite of standalone quality and document management solutions to deliver transparency and insight.

QUALITY MANAGEMENT MODULES INCLUDE:

- **CAPA:** Manage corrective and preventative actions used for continuous improvement in quality and processes.
- **Deviations / Non-Conformance:** Automate and manage deviations and OOS from occurrence to investigation and closure.
- **Complaints:** Manage recording, routing, and resolution of all customer complaints.
- **Change Control:** Control changes or modifications to products and processes together with the management of associated tasks.
- **Audit Management:** Provide complete tracking of observations, findings, and recommendations.

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