RegDocs
connect

An Advanced Regulatory EDMS & Submission Planning Solution

RegDocs Connect gives your operational and regulatory teams the tools they need to prepare complete and compliant submission-ready documents and records. Automated workflows manage your records lifecycle from draft to final, enabling your team to be in complete control of your regulatory documents at all times. Based on the EDM reference model and eCTD, RegDocs Connect facilitates the planning and development of regulatory submissions, going beyond traditional EDMS systems.

- Streamline submission document review and approval
- Improve author productivity for submissions
- Integrate with mainstream eCTD solutions to facilitate the building of sequences
- Increase visibility of regulatory activities

Pre-Defined Configuration

RegDocs Connect comes preconfigured with all of the different regulatory document types, metadata, and planning tools needed to prepare complete and compliant regulatory submissions.

Real-time Submission Readiness

Regulatory teams can easily drill down through real-time, interactive reports to answer questions about progress and submission readiness. Throw out your excel trackers, and have your team and your affiliates work in one place.

Fast Implementation & Onboarding

Our optimized implementation process and cloud deployment can get you live in a matter of weeks. We take care of a large part of the validation effort, provide you with a comprehensive documentation pack and customize the training to suit your needs.

Easy to Use

The Connect Platform has been designed with the end user in mind, crafting a totally unique and intuitive experience for the entire team, whether they're familiar with technology or not.

Accessible Anywhere

Internal & external teams can access the system from a single, secure, cloud location from any device, anywhere in the world. No need to bring users behind corporate firewalls or issue laptops, network IDs, or tokens.

Accelerated Validation

In order to shorten implementation timelines, Montrium's expert delivery team performs the Installation Qualification (IQ) and Operational Qualification (OQ) ahead of time, providing you with a detailed set of documentation perfect for an auditor or inspector.

connect

Automate the Regulatory Submission Planning Process

RegDocs Connect is a modern cloud application for authoring and managing regulatory submissions content. Through our integrated tools, pharmaceutical and biotechnology companies gain greater access, visibility, and control over their submissions information.

Regulatory Document Template Center

Author regulatory submission content from a library of regulatory templates centrally managed by your team.

Automated Document Workflows

Flexible workflows drive the document lifecycle, guiding the users through authoring, reviewing, and approval of submission content.

Centralized Authoring & Collaboration

Work fast when your team has a deadline. Integration with Microsoft Office and allows real-time collaborative authoring on regulatory documents.

Submission Readiness Reporting & BI

Gain critical visibility into submission readiness to understand what is required, final, and still outstanding.

Dynamic Placeholders & Doc Classification

Placeholders for required documents are automatically generated, and once fulfilled, assigned the relevant metadata, reducing manual overhead.

PDF/A Rendering Engine & Digital Signatures

Quickly render and digitally sign documents with a 21 CFR Part 11 validated tool directly integrated in RegDocs Connect.

Correspondence & Committment Tracking

Centrally manage regulatory communications and information through powerful correspondence and commitment tracking.

eCTD Mapping & Export Tools

Documents are automatically mapped to the EDM reference model and eCTD modules aligning your content taxonomy with industry best practices.

Global Submission Planning Tool

Centralize regulatory submission planning in one place, combining approved regulatory content with ongoing submissions to significantly reduce timelines.

connect

for more information visit **montrium.com**