Simplify Document Lifecycles and Increase Efficiencies

Submission data is growing exponentially. New approaches to effectively manage data from author-to-archive improve operational efficiencies and accelerate time to market.

RegDocs365™ EDM unifies content, workflows and business processes in a cross functional collaborative and Audit Ready Compliant Cloud™ (ARCC) validated environment to deliver the single source of truth at every phase of the drug development process.

RegDocs365
EDM Delivers

Flexible and Scalable Architecture

We grow as you grow. RegDocs365 is an easy to deploy, path-to-scale, pre-validated solution enabling sophisticated metadata, searchable content features for quick submission review with extensive capabilities.

- One of the most cost-efficient, configurable, compliant EDM solutions on the market
- Get up and running in weeks with no on-staff IT required
- Preconfigured to DIA EDM reference model
- Seamless eCTD publishing integration
- Built to emerging industry best practices
- Integrated with SOPs, quality and training modules
- Benefit from a sound data governance framework
- Bulk move and copy features between EDM & eTMF libraries

Sophisticated EDM

Unify content, manage seamlessly, and access any content type (documents, data, voice, and video) on demand in an Audit Ready Compliant Cloud environment.

- Meets FDA, 21 CFR Part 11 requirements
- Compatible with all file types including popular office productivity suites (DOC, XLS, OCF), image files (JPEG, TIFF, PNG), email, web standard (XML, HTML), voice and video
- Easily create a file management hierarchy for libraries, folders and files
- Route information with simple-to-use workflows; Intelligent digital workflow, document control, built in access controls and cross-linking
- Configurable taxonomies to create folder hierarchy for easy file management
- Advanced architecture allows auto naming, versioning, data lineage and data traceability
- Intuitive queries structured and unstructured searches
- Sophisticated metadata indexing offers high-throughput, quick document search and retrieval to summary reports
- Intuitive file storage structure - quickly locate and retrieve any document or content
- Smart features provide side-by-side content and meta-data viewing
- Streamline submissions and quickly produce FDA-ready PDFs

Compliance and Regulatory

Future-Proof Compliance Integrity -- Author-to-archive content in an Audit Ready Compliant Cloud (ARCC) Environment.

- PDF renditions that meet FDA requirements
- Embedded fonts and watermarks
- Integrates with eCTD publishing tools
- Allows drag and drop to maintain links
- Meets 21 CFR Part 11 requirements for all content types
- GxP Audit ready
- Configured to IND, DMF, ANDA, NDS, NDA, BLA, MAA submissions
- Compliant e-signatures
- SOPs, quality, and training modules

Security & Long-Term Archiving

Safeguard your digital content over decades with robust security and long-term archiving in a regulatory, compliant environment.

- Long-term, active digital preservation-- access content today or in decades from now
- Digital preservation with full version history
- Manage security authentication per user
- Set granular permissions at the file or document level
- Version control with full version history preservation

Intelligent Collaboration

Real-time collaborative tools help remote and in-house teams achieve greater levels of transparency and efficiency.

- Enhance collaboration and accelerate decision-making with remote instant access
- Streamline document creation, reuse, editing, authoring, and approval in a regulatory environment
- Leverage automatic indexing, co-authoring capabilities, and compliant e-signatures
- Utilize automated workflows to improve team synergy
- Automatic OCR features to easily enable indexing of essential documents
- Intuitive file storage structure - quickly locate and retrieve any document or content
- Configurable workflows to author and edit documents in parallel and in real-time

Why Choose RegDocs365 EDM

Scale-Up Licensing
Easily scale-up as your number of submissions grows

Data Traceability
Expanded versioning and audit trails

Cloud Optimization
No IT required. Enables cloud-first strategy

Operational Efficiency
Intuitive file storage structure
Automated workflows & co-authoring

Rapid Implementation
Reduce setup time from months to weeks

OCR & Metadata Indexing
Quick document retrieval

Resilient Architecture
Quality & compliance built in

Minimize Rework
Shorten time to submission

About Us

RegDocs365™ is a life science digital content and document repository solution hosted in an Audit Ready Compliant Cloud™ (ARCC), FDA 21 CFR Part 11 environment. Our comprehensive solution brings chaos into order; streamlines, manages, and future-proofs data; and delivers the single source of truth from author to archive.

RegDocs365 Solution Suite

EDM | eTMF | Life Science Basic | FDA Form 1572

Clinical Collaboration | Content Management | Custom Solutions

RegDocs365
Life Sciences IT Solutions

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