

ENNNOV REGULATORY SUITE

Ennov Regulatory Documents Enterprise Document Management Software

A comprehensive, flexible, scalable and secure document management solution designed to help you streamline processes and increase operational efficiency while eliminating regulatory compliance risk.

The Regulatory EDMS Challenge

Authoring, reviewing, approving and tracking documents that are destined for global regulatory submissions can a challenge. Submission teams across multiple departments and locations must collaborate effectively to ensure that timelines and agency commitments are met.

Storing documents on file shares across disparate locations and emailing them among team members is inefficient, impedes productivity and introduces risk. Regulatory Operations staff often needlessly spend time hunting for the correct version of documents—prolonging their tasks at hand and increasing the possibility of missed deadlines.

Unified Access to All Documents

Ennov Regulatory Documents provides a comprehensive solution for managing regulatory submission documentation. The document inventory is preconfigured in alignment with the DIA EDM Reference Model and includes all required domains, groups, subgroups and artifacts.

Ennov's intuitive user interface and efficient search capabilities allow every employee to quickly locate and access the documents they require. Our intuitive suite of design utilities allow administrators to configure and manage the system without needing IT skills. Ennov's scalability and security enables you to safely manage large volumes of documents—making it the perfect solution for global deployments.

> CORE CAPABILITIES

- Pre-configured document inventory
- Advanced life cycle management
- Flexible rights management
- Automatic PDF rendering
- Full text and metadata based searching
- Controlled printing, copy and paste
- Periodic review, expiry and archiving
- MS Office 365 and Google Drive connectivity

> KEY FEATURES

- Integrated worklist dashboard
- Configurable document types, workflows and views
- Automated email notifications
- Intuitive user interface
- Integrated PDF viewer
- Composite document support
- 21 CFR Part 11 compliant
- 100% web-based



Cloud Based or On Premises



Multi-Platform



ISO 9001 and 27001 Certified

Regulatory Documents - Part of the Ennov Regulatory Suite



**REGULATORY
DOCUMENTS**



**ENNOV
DOSSIER**



**ENNOV
RIM**



**ENNOV
IDMP**

Why Choose Ennov?

HUNDREDS OF COMPANIES TRUST ENNOV

Over 25 years' experience, and 450+ Life Science customers, with many more in other industries.

Modern architecture and user interface: 100% web-based. Highly scalable. User-centric design.

Our commitment to your success: Very high customer satisfaction. 98.5% of projects delivered on time and within budget.

PROVIDING YOU FREEDOM OF CHOICE

Available as cloud-based or on-premises deployment: You can switch between deployment options at any time.

We make you autonomous: System configuration and management require no IT skills.

Improved security and optimized performance: Data is hosted locally for total flexibility. Single tenancy minimizes business interruptions.

Learn more about our unified content and information management platform to support the entire Life Sciences product development continuum at www.ennov.com



QUALITY

Our comprehensive QMS improves operational efficiency and ensures regulatory compliance



CLINICAL

Our total solution for capturing and managing Clinical Trial information streamlines clinical operations



REGULATORY

Our world-class Regulatory content and information management software accelerates HA approvals



PHARMACOVIGILANCE

Our end-to-end solution for collecting, reporting and analyzing human and vet PV data minimizes risk



COMMERCIAL

Our complete management of professional events ensures DMOS, EFPIA, HCP and COI compliance

About Ennov

Ennov offers a unified compliance platform to power solutions that span all regulated business areas (Regulatory, Quality, PV, Clinical, Commercial). From leading pharmaceutical companies to start-up biotechs, we proudly serve over 450 companies and 500,000 users worldwide.

For more than 25 years, we have been developing innovative, powerful and easy-to-use software for regulated content, data and process management. Our solutions are designed and built to support the entire Life Sciences R&D continuum. Ennov is ISO 9001 and 27001 certified for all software products, and processes and we boast a 100% success rate in customer audits.

Raleigh



Paris



Cambridge



Tokyo