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ENNOV REGULATORY SUITE

Ennov Dossier

Regulatory Dossier Management & Submission Publishing Software

A complete and scalable dossier management and submission publishing solution that helps regulatory teams create, manage, validate, publish, review, and maintain compliant submissions across global health authority requirements and formats.

The Publishing Challenge

Regulatory operations teams must produce compliant submissions across a growing mix of formats, regions, and lifecycle requirements. Standard, eCTD, NeeS, vNeeS, eCopy, and sequence-based dossiers all require accurate structure, metadata, content, validation, and version control.

When documents, dossier structures, and publishing activities are managed separately, teams spend too much time locating the right files, confirming approved versions, rebuilding content, and tracking submission history. This creates rework, slows publishing, and increases compliance risk.

Organizations need one intuitive and unified publishing platform connected to controlled regulatory content, with the flexibility to support global requirements and the visibility to manage dossiers through every sequence and submission lifecycle.

Efficient and Intuitive Publishing

Ennov Dossier helps teams build, manage, publish, validate, review, and maintain regulatory dossiers using the native capabilities of Ennov Regulatory Documents. Publishers can add approved documents directly through search, views, or drag-and-drop, while managing current links, fixed links, internal files, and reusable content within one controlled dossier structure.

Configurable templates support Standard, eCTD, NeeS, vNeeS, eCopy, and sequence-based dossiers. Teams can manage eCTD sequences, lifecycle operations, Study Tagging Files, cumulative views, and submission history while keeping content synchronized with the latest approved document versions.

Interactive viewing, progress tracking, incremental publishing, validation, and package extraction help regulatory teams improve submission quality, reduce processing time, and maintain compliance.

> CORE CAPABILITIES

- Standard, eCTD, NeeS, vNeeS, eCopy, and sequence-based support
- Dossier versioning, revisions, and lifecycle tracking
- eCTD sequence and operation management
- Study Tagging Files and metadata management
- Electronic and PDF volume publishing
- Integrated validation and progress tracking

> KEY FEATURES

- Native connection with Ennov Regulatory Documents
- Configurable templates, sections, nodes, and links
- Intuitive drag-and-drop dossier assembly
- Current links, fixed links, and internal references
- Content synchronization and reuse
- PDF splitting, merging, and volume viewing
- Full-text search and exportable progress reports

Cloud Based or On Premises | **Multi-Platform** | **ISO 9001 and 27001 Certified**

Ennov Dossier - Part of the Ennov Regulatory Suite

ENNOV DOC | 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