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ENNOV REGULATORY SUITE

Ennov Dossier
Regulatory Submission Publishing Software

A complete and scalable dossier management and submission publishing solution that is suitable for regulatory operations of all sizes and produces output that is compliant with all current health authority requirements.

The Publishing Challenge

The efficient production of compliant regulatory submissions is the goal of every regulatory operation. While the benefits of electronic submissions are well documented, the transition from paper to electronic filings is still in process globally. This situation is forcing many companies to continue to prepare submissions in both formats.

Clearly with that amount of disparity remaining in the industry, having one publishing platform that can effectively produce a variety of submission output formats provides a distinct advantage in terms of flexibility, training and total cost of ownership. The platform must be easy to use and ideally connected to the repository used to store and manage submission related documents.

Efficient and Intuitive Publishing

Ennov Dossier provides the ability to build, manage, publish, validate and archive regulatory dossiers using the native capabilities found within Ennov Doc. This eliminates the fragmented and inefficient processes of locating, copying and uploading the documents that you need for your regulatory submissions—providing a harmonized and seamless dossier publishing solution. A simple drag-and-drop interface allows publishers to link documents into submission assemblies quickly and easily.

Submission assembly templates are provided for the regions that accept eCTD submissions (e.g. US, EU, GCC, Canada, Swissmedic, TGA) as well as for other non-eCTD formats and can be modified to meet a client's specific requirements. Ennov provides regular updates to these templates as the regulatory guidance changes.

> CORE CAPABILITIES

- CTD, eCTD, NeeS, VNeeS and eCopy support
- Dossier life cycle management
- eCTD sequence and metadata management
- Robust hyperlinking and bookmarking
- Integrated eCTD validator
- Built-in submission assembly templates

> KEY FEATURES

- Intrinsically connected to Ennov Doc
- Intuitive drag-and-drop user interface
- Compatible with any WebDAV compliant repository
- Full text and metadata based searching
- Automatic compliant PDF rendering
- 21 CFR Part 11 compliant
- 100% web-based

Cloud Based or On Premises | **Multi-Platform** | **ISO 9001:2015 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	PROVIDING YOU FREEDOM OF CHOICE
20 years and 300+ Life Science customers, with many more in other industries.	**Available as cloud-based or on-premises deployment:** You can switch between deployment options at any time.
Modern architecture and user interface: 100% web-based. Highly scalable. User-centric design.	**We make you autonomous:** System configuration and management require no IT skills.
Our commitment to your success: Very high customer satisfaction. 98.5% of projects delivered on time and within budget.	**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 300 companies and 300,000 users worldwide.

For more than 20 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 9001:2015 certified for all software products and processes and we boast a 100% success rate in customer audits.

Raleigh › **Paris** › **Cambridge** › **Tokyo**