ennov
Software for Life

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
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

- **Over 15 years of experience providing EDMS solutions**
  200+ life sciences customers, 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

Headquartered in Paris, with offices in the US and UK, Ennov provides the most original, comprehensive, and cost-effective suite of software solutions for the Life Sciences industry. From leading pharmaceutical companies to emerging biotechs, we proudly serve over 150 companies and 150,000 users around the world.

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 including Clinical, Regulatory, Quality, Pharmacovigilance and Commercial. Ennov is ISO 9001:2015 certified for all software products and processes and we boast a 100% success rate in customer audits.

Contact Ennov

Phone: +1 (833) 366-6887 | Email: contact-us@ennov.com

Raleigh, NC | San Jose, CA | Paris, FR | Cambridge, UK