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ENNOV REGULATORY SUITE

Ennov RIM
Regulatory Information Management Software

A purpose-built application (based on Ennov Process) for the management and tracking of therapeutic product details, registration information, regulatory project plans and activities, agency correspondence and commitments.

The RIM Challenge

Regulatory information management at global organizations is rarely integrated and usually consists of collections of spreadsheets, homegrown databases, emails and ad hoc reports—each full of redundant and/or inconsistent data.

However, as product registrations become increasingly complex and volumes increase, companies are realizing that the ability to answer business-critical questions about all regulatory activity in an efficient and timely manner is critical to effective operations that ensure enterprise-wide compliance. These and other factors underscore the need for robust Regulatory information management capabilities.

A Single Authoritative Source

Imagine all of your regulatory information regarding products, registrations, submissions, correspondence and commitments in one centralized place accessible from anywhere. With Ennov RIM, life sciences companies can streamline their regulatory processes, improve their data quality, quickly answer business-critical questions and effectively respond to health authority requests.

The 100% web-based solution includes an intuitive and configurable user interface, regulatory task management, e-mail notification capabilities and correspondence and commitment tracking functions. Ennov RIM's Regulatory activity planning feature provides the ability to manage submission projects that span many applications—information is entered once and replicated across products, countries and applications as appropriate.

> CORE CAPABILITIES

- Centralized management of product information
- Market authorization and registration management
- Regulatory project planning and activity tracking
- Automatic linkage between substances, products, reg-istrations, activities, dossiers, submissions and documents
- Correspondence and commitment tracking
- Variation change control management

> KEY FEATURES

- Role-based access rights
- Configurable data model
- Automated email notifications
- Robust querying and visual dashboards
- Intuitive user interface
- Graphical workflow designer
- 21 CFR Part 11 compliant
- 100% web-based

Cloud Based or On Premises | **Multi-Platform** | **ISO 9001:2015 Certified**

Ennov RIM - Part of the Ennov Regulatory Suite

Why Choose Ennov?

HUNDRED OF COMPANIES TRUST ENNOV	PROVIDING YOU FREEDOM OF CHOICE
Over 20 years of experience providing BPMS solutions 300+ life sciences customers, 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	We make you autonomous
100% web-based, Highly scalable. User-centric design.	System configuration and management require no IT skills.
Our commitment to your success	Improved security and optimized performance
Very high customer satisfaction. 98.5% of projects delivered on time and within budget.	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