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.



Cloud Based or On Premises



Core Capabilities

Centralized management of product information

Market authorization and registration management

Regulatory project planning and activity tracking

Automatic linkage between substances, products, registrations, activities, dossiers, submissions and docu-

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



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Over 200 Life Sciences Companies Around the World Use Ennov Software

Ennov RIM - Part of the Ennov Regulatory SuiteImage: Second s

Why Choose Ennov?

Hundreds of companies trust Ennov

- Over 15 years of experience providing BPMS 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



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



Our world-class Regulatory content and information

management software

accelerates HA approvals

y Pharmacovigilance latory Our end-to-end solution for collecting, reporting and

collecting, reporting and analyzing human and vet PV data minimizes risk



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

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