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ENNOV REGULATORY SUITE

Ennov RIM for Medical Devices

A dynamic, all-in-one regulatory information management solution crafted for medical devices, pharmaceuticals, and combination products. The platform ensures continuous compliance, supports operational agility, and minimizes the risk of non-compliance across diverse global markets.

Precision Management of Global Regulatory Challenges

Managing regulatory information and documentation for medical devices involves navigating a complex landscape of global regulatory requirements. For medical device companies, ensuring regulatory compliance while maintaining the agility to innovate and respond to market demands is crucial. This challenge is exacerbated when data and documents are scattered across multiple systems, making collaboration difficult and increasing the risk of non-compliance or delays in product launches. Moreover, companies that produce medical devices, pharmaceuticals, and combination products face even more intricate challenges.

These complexities require a strategic approach that can seamlessly handle both regulatory and quality data and documentation. The ideal solution would integrate these processes, prevent data fragmentation, streamline collaborations, and ensure a unified response to the diverse regulatory landscapes.

Centralized Compliance in a Unified Platform

Ennov RIM for Medical Devices simplifies the complex regulatory landscape inherent to the medical device industry with a purpose-built, device-centric data model. This model connects your quality documentation with your regulatory documents and data, streamlining the effort to bring devices to market.

With a best-in-class user interface and a comprehensive yet flexible data model, Ennov RIM for Medical Devices supports the rapid pace of device innovation and the diversity of development. Our built-in templates offer quick alignment with regional regulatory standards for your documents, while our core data model natively supports UDI-oriented requirements such as EUDAMED and GUDID.

As the only platform in the market that truly unifies regulatory and quality documentation, it sets a new standard in comprehensive compliance management. By uniting these essential functions, Ennov RIM minimizes operational risks, accelerates market entries, and prevents the pitfalls of data fragmentation. Teams of all sizes can collaborate more effectively using the same intuitive interface for both quality and regulatory processes.

Comprehensive tracking and reporting features offer real-time visibility into submission statuses, certifications, and regulatory commitments. Ennov RIM for Medical Devices combines precision and flexibility, ensuring seamless compliance and global operational excellence—making it the essential choice for medical device industry regulation.

> CORE CAPABILITIES

- Medical Device, Drug, and Combination Product data model
- Built-in re-usable and adaptable templates for device documentation
- Integrated platform for quality and regulatory documents and data
- UDI data capture for EUDAMED and GUDID
- Real-time regulatory tracking and reporting

> KEY FEATURES

- Intuitive, efficient user interface design
- Comprehensive document and submission tracking
- Unified regulatory management dashboard
- Configurable data fields, templates, and regulatory workflows
- Automated notifications for regulatory milestones
- 100% web-based platform

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

Ennov RIM - 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.	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