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ENNOV REGULATORY SUITE

Ennov RIM for Medical Devices

A tailored, agile, and comprehensive regulatory information management solution designed specifically for medical devices, enabling seamless global compliance, enhancing operational agility, and reducing the risk of non-compliance in the fast-evolving medical device landscape.

The Medical Device Regulatory Challenge

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.

Unified Solution for Device-Specific Needs

Ennov RIM for Medical Devices addresses 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 interface and a global, flexible structure, 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.

Additionally, the platform's native support for quality documents and processes enables a seamless connection into the regulatory world. Large teams will more seamlessly work together while small teams will enjoy the same intuitive interface for both quality and regulatory.

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-centric data model
- Re-usable and adaptable built-in templates for device documentation
- Integrated platform for quality and regulatory documents and data
- UDI data capture for EUDAMED and GUDID
- Intuitive and user-friendly interface
- 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 and 27001 Certified**

Ennov RIM - Part of the Ennov Regulatory Suite

Why Choose Ennov?

HUNDREDS OF COMPANIES TRUST ENNOV	PROVIDING YOU FREEDOM OF CHOICE
Over 25 years and 450+ 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 450 companies and 500,000 users worldwide.

For more than 25 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 and 27001 certified for all software products and processes, and we boast a 100% success rate in customer audits.

Raleigh › Paris › Cambridge › Tokyo