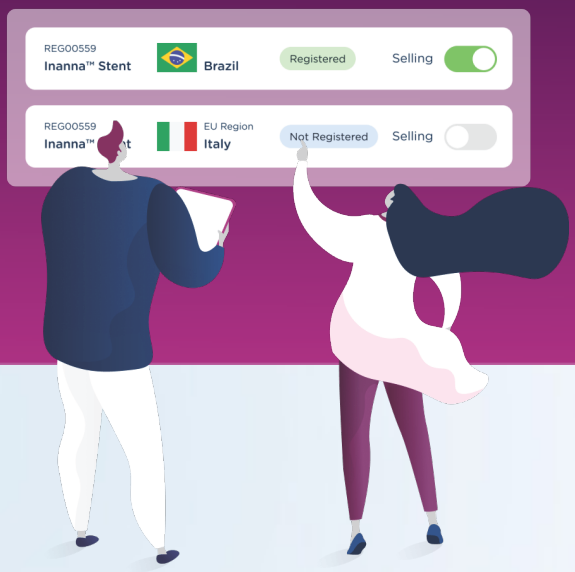
Rimsys®

Regulatory management for medical technology

Growing global complexity is creating major challenges



Regulatory affairs teams face a complex global environment with growing requirements, heavier enforcement, and cross-country collaboration among regulators. By some estimates these changes will force up to 75% of products to be removed from the market.[1]

Nearly 92% of medtech RA professionals work on regulatory functions in more than one country. Keeping pace with accelerating regulatory changes using traditional approaches (spreadsheets and expensive external consultants) simply isn't sustainable. Regulatory management directly impacts revenue, making it essential for RA teams to have access to **accurate information** and **organized systems**.

Top issues

Disorganized information

65% of regulatory professionals require at least a week to gather the information needed to determine where their products are sold and/or registered.

Many teams use a combination of manual tools to track this critical and complex information:

- Spreadsheets
- Email reminders
- File systems
- Paper-based storage

Wasted resources

Up to **50%** of a regulatory team member's time is spent simply looking for information.[2] With an average salary of **$99,211**[3] that means nearly **$50,000 per employee** is wasted due to inefficient processes.

Worse, many companies try to fill this resource gap using external consultants - spending **hundreds of dollars per hour** to complete manual administrative tasks.

Major noncompliance risks

If your RA team was audited under the Medical Device Single Audit Program (MDSAP) **would you be ready?**

- Did you comply with requirements to register and/or license your medical device manufacturing location(s)?
- Did you submit medical device listing information to the appropriate regulatory authorities?
- Did you obtain marketing authorization in the countries that you are selling?
- Do you have a system to monitor registration expirations?
- Do your sales, customer services, and regulatory teams always stay on the same page?

Business impacts

Loss of reputation and revenue

Missing registration dates, slow-to-market losses, and long-term impacts such as loss of customer loyalty have an immediate impact on market capitalization. An improper product release due to lack of registration status visibility can cause fines, and force a product withdrawal.

Delay in time-to-market

There's a lot that goes into getting a medical technology product to market. Regulatory inefficiencies prolong time-to-market, increasing product costs, delaying revenue, and can result in noncompliance penalties.

Lack of collaboration

Regulatory processes touch multiple functional areas, and traditional regulatory solutions merely piece together disparate, manual systems to achieve marginal improvement. These approaches inhibit the accurate and timely transfer of information, and disrupt cross-functional workflows.

Risk of noncompliance

In the medtech industry, product releases must be compliant. Regulators from different markets are working together to identify instances of noncompliance as well as misalignment of information in submissions and other communications.

Turnover of critical employees

Employee turnover on regulatory teams is linked to overwork and stress. Inefficient or wasteful processes significantly contribute to this problem. It's critical that employees are able to perform efficiently with accurate information and useful technology.

Gaps in company knowledge

Having a fail-safe in place for when (not if) experienced RA professionals leave prevents loss of company, product, and regulatory "tribal knowledge". Getting new employees up to speed without subject matter expertise can cause delays and waste time.

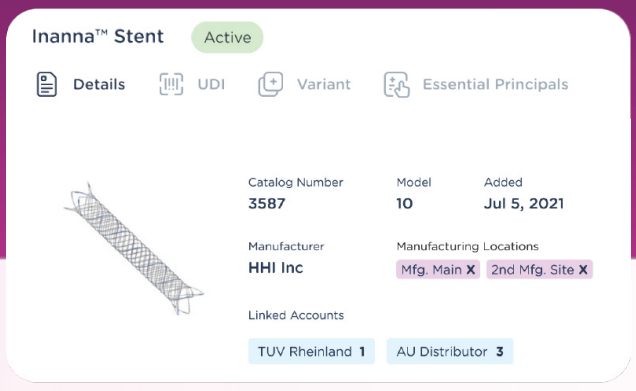
The solution: holistic medtech-focused regulatory information management (RIM)

Rimsys helps RA teams corral and manage all of the information they need to do their jobs. It centralizes product details, registrations, certificates, UDI data, technical files, and GSPR/essential principles tables.

Rimsys streamlines and provides a traceable record of regulatory activities across the product lifecycle. It provides access to high-quality regulatory intelligence, allows teams to collaboratively author and assemble regulatory submissions, and automatically monitors expirations, international standards, and changing global regulations.

Using Rimsys, medtech companies have:

- Reduced workload associated with product releases by 88%
- Reduced time spent on GSPR maintenance by 99%
- Eliminated the need for 15 external consultants



Real results - A leading global dental adhesives manufacturer reduces essential principles & GSPR maintenance time by 99%

A leading global manufacturer of dental adhesives and cement sells over 50 different product lines in more than 90 countries around the world. Most of their regulatory work was managed using traditional productivity software - documents & spreadsheets. Regulatory docs were stored in a file system, and most of their collaboration happened via email.

With Rimsys, they were able to centralize product, registration, and certificate information, and digitize 88 essential principles tables. Now they can find information much more quickly, collaborate with distributors directly, and automate updates to their technical files.

> We've taken a process that could take a week or a week and a half all told, and shortened it to a matter of minutes

-Global RA Manager

About Rimsys

Rimsys is bringing regulatory order to the medtech industry. The Rimsys Regulatory Information Management (RIM) platform digitizes and automates regulatory activities, freeing teams from inefficient administrative work, and helping them confidently establish and secure global regulatory compliance. Unlike complex spreadsheets, or expensive consultants, Rimsys streamlines all regulatory activities in an integrated platform, helping medtech companies get to market more quickly and reduce risk of non-compliance, product recalls, and unexpected expirations.

Contact us for a free custom demo

rimsys.io letschat@rimsys.io

1 MedTech Europe survey of 115 medtech companies, 2021
2 Deloitte: Growing regulatory's strategic value: The value of a holistic Regulatory Information Management (RIM) capability, 2018
3 RAPS: Scope of Practice & Compensation Report for the Regulatory Profession, 2021

Rimsys®