Rimsys® | Regulatory Management Software

# CASE STUDY

## Global MedTech Registration Digitization

# SITUATION

Discover how Rimsys digitized and automated global medical device registrations for a $2 billion (USD) medical device manufacturer with 15,000 products (i.e., SKUs) in 100+ countries, utilizing an off-the-shelf, product-centric global MedTech regulatory software platform.

## KEY DELIVERABLES

### DIGITIZE

Automate global product registrations

Improve product release authorization (i.e., regulatory approval)

Automate notification of registration expirations to relevant stakeholders

### REDUCE

Compile the full technical and premarket application documentation globally

Eliminate inefficient manual, disjointed and paper-based processes

Remove compliance and revenue risks

### IMPROVE

Streamline collaboration and shared documentation with economic operators

Enhance storage, retrieval, and management of regulatory information and documentation

Adjust reports to track relevant KPIs specific to regulatory affairs (i.e., performance)

# SOLUTION

The Rimsys team worked directly with key customer stakeholders to fully understand and analyze their existing medical device registration process in order to address:

» Existing gaps that resulted in errors in processing, inefficiencies, or administrative overhead

» Potential barriers to digitization, or procedural steps requiring excess manual intervention

» Opportunities to batch process steps and create repeatable and scalable workflows

The newly formed to-be process was mapped to workflows either already inherent to the Rimsys platform, or in some cases additional workflow steps were added to address unique process needs.

## INTEGRATIONS

The customers' existing software solutions' (PLM, eQMS, and ERP) interfaces were integrated into Rimsys, allowing the team to fully leverage Rimsys' powerful integrations.

### PLM

Integrate with the existing PLM software to synchronize existing product master data.

### QMS

Integrate with the existing QMS to pull quality documentation and records directly into Rimsys to build full technical documentation and premarket applications.

### ERP

Integrate with the existing ERP software to enable automatic regulatory blocks for unregistered, expired, or non-sellable products.

## KEY OUTPUTS

Replaced the static, often outdated, or inaccurate, color-coded Excel spreadsheet managing 15,000 SKUs in 100+ countries

Created greater visibility for associated products and regulatory approval status to improve regulatory workflow

Identified negative trends and improved inefficiencies in regulatory workflows

Centralized cloud-based storage and timely recall of regulatory documentation

Migrated all static regulatory product approvals from Microsoft SharePoint to the dynamically updated Rimsys platform

Provided improved traceability of interactions with project team tasks, correspondence with regulatory authorities, and tracking regulatory processes

# RESULTS

## REDUCED TIME-TO-MARKET AND NON-VALUE-ADDED ADMINISTRATIVE WORK

The prior process of product release authorizations involved a manually created and maintained color-coded Excel spreadsheet with 15,000 SKUs in 100+ countries. Moreover, the prior process involved several team members and took several weeks to review documentation, provide feedback and edits, and await for formal signoff. This often resulted in outdated data or inaccurate updates, creating significant risk for the regulatory team in the company overall.

The prior product release authorization process involved **four (4) team members**, including one (1) Sr. Regulatory Affairs Specialist, two (2) Quality Assurance (QA) Engineers, and one (1) Document Control Specialist.

> *Once Rimsys was implemented, the regulatory release authorization process was modified so it was 100% independent from QA and the product shipping status was maintained and controlled within Rimsys. This meant there was no need for additional QA review, edits and approval of documentation, and there was no need to process any documentation through Document Control. The four (4) team members associated with the prior process were reduced to one (1) team member and reduced the remaining one (1) team member's workload by 50% per week.*

Moreover, as the prior process involved several teams, it often took weeks to get a formal product release authorization approved. **With the implementation of Rimsys, the regulatory release authorizations were instantaneous, and customer service did not need to wait for formal document processing associated with the prior process, significantly reducing the lead time of shipments and sales orders.**

## INCREASED REGULATORY DATA QUALITY

Global registrations were managed on a color-coded Excel spreadsheet, which was prone to human error, inconsistencies, and manual processing. The data maintained within the spreadsheet was only 75% accurate. A significant number of resources would have been needed to improve the error rate because it was such a manual process. This caused potential compliance and revenue-risks for the company.

> *By implementing a fully validated Regulatory Information Management (RIM) solution, the manual, disjointed, and paper-based processes were completely eliminated. This also significantly increased compliance and reduced any revenue-risk associated with sellable products.*

# RESULTS

## GAINED CONFIDENCE & VISIBILITY IN REGULATORY DATA

The prior process of managing regulatory information was manual and not designed to output key performance indicators or structured reports to make timely decisions. Significant time and resources were needed just to identify the list of countries where a product was marketed. This often took several hours.

> *With the implementation of Rimsys as a fully validated system, that task now takes less than 5 minutes to complete, regardless if it is one product in a single country or thousands of products in every country of the world.*
>
> *Moreover, the ability to monitor global license expirations was completely dependent on and outsourced to the distributors. The company had zero visibility to critical revenue-impacting data.*
>
> *All data is now maintained centrally, in-house with automatic notification of upcoming expirations and the ability to automatically change selling status based on expired or changed licenses.*

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Rimsys is a provider of world-leading Regulatory Information Management (RIM) software for medical technology companies. Built by and for regulatory affairs professionals, Rimsys digitizes, automates, and creates regulatory order to ensure products adhere to changing global regulations. It is the only holistic RIM software for medical devices, in-vitro diagnostics, and medical device software that makes it easy to manage global UDI requirements and navigate the pillars of regulatory affairs, including product registration, standards management, essential principles/ GSPR, and regulatory intelligence.

## READY TO DEMO RIMSYS WITH YOUR TEAM? CONTACT US!

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