Rimsys® | Case Study

A leading global microbiology manufacturer makes regulatory information instantly accessible

Microbiology division of a global life sciences corporation

Products:

Reagents for microbiology research

Regulatory automation:

Registrations for 5000+ products in 80+ countries

About

The microbiology division of a global life sciences corporation had challenges with the management of its product and registration data. The division develops reagents for microbiology research including dyes, kits, and assays. Most of these 5,000+ products are subject to regulation as in vitro diagnostic tools or medical devices. With products manufactured across 11 locations, and globally dispersed teams, keeping track of product and registration across 80 different countries was becoming more difficult.

The situation: highly siloed product and registration information

Each manufacturing location had its own store of product and registration information (often based in spreadsheets), and used its own format. As a result it was difficult for team members, unless they were on-site, to know where and how to access data. “From a compliance perspective, the situation was challenging,” said a Sr. Regulatory Affairs Manager. “Especially with the MDSAP regions where registration requirements are changing. Monitoring all of your products, and keeping track of countries where they are registered with a portfolio the size of ours gets complicated pretty quickly.”

Having a handle on product registrations is an important component of the audit process, and one that the regulatory affairs department struggled with. “I’ve sat in the MDSAP audits with our Notified Bodies where they would ask ‘where is this product registered?’, and we’d struggle to get this information out of old databases. We would get it eventually, but it was never available at our fingertips.”

The regulatory affairs team also had to handle a lot of internal requests for information. Traditionally these requests were sent and responded to via email. Depending on time zones it could sometimes take hours to get information. With no document management or controls on email this made request processes largely unmeasurable.

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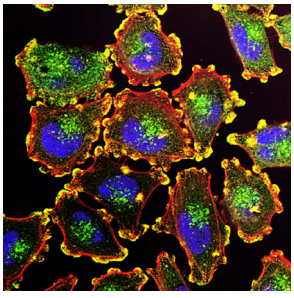
The solution: centralized regulatory information management

The lack of centralized information was hurting the efficiency of the team, and they knew the current approach simply was not sustainable. With the imminent arrival of IVDR in Europe, the team needed a better way to manage all of their regulatory information. "IVDR is a big shift in the industry," said the RA manager. "But it is bigger than just Europe. Malaysia is already asking for the same things. The whole ASEAN region is following Europe's lead. We have to update all of our technical documentation, and ensure that our essential principles and GSPRs are up to date. A lot of countries will be asking for this in the future."

The RA team turned to their IT business partners to set about digitizing product information, and automating registration processes. They developed a process improvement roadmap, with the first step being to harmonize all of the disparate product data, and get it ready to pull into a central database. They then looked at RIM systems that could function as that data hub for the team. They began their search looking at some content management tools and regulatory information management solutions for pharmaceutical companies, but none of the initial tools provided the medtech-focused information structure they were looking for.

Rimsys was different. Because it is designed specifically for medical device and IVD product registrations the RA and IT teams felt that it would be a perfect fit for their data needs. They were able to pick it up quickly, and transfer all of their registration and license information from individual manufacturers to the centralized system. "We will have every bit of data associated with our products in the system," said the RA manager. "All product registrations are going into the system, and



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– Sr. Regulatory Affairs Manager

the majority of our licenses are there now as well. Next year we will be adding UDI data, product hierarchies, and GSPR checklists."

Results: more efficient information flows, and greater global compliance

The new system has made information access much easier. Now any time global teams need registration information, they can quickly log in and access it without having to send a request, or dig through individual manufacturers' data. "It's a matter of seconds versus hours now to find information. Instead of waiting for someone to get back to you, you can just go to that central database and the information is there straightaway."

The project management features have helped to put some structure around information requests as well. Now when requests for registration or product information come in from channel partners, the market access team enters the request via Rimsys. Tasks can be assigned and individuals notified directly in the platform—giving the team visibility into and the ability to measure processes.

About Rimsys®

Rimsys is bringing regulatory order to medtech. The Rimsys platform digitizes and automates regulatory activities, freeing teams from administrative work, and helping them establish and secure global compliance. Rimsys organizes regulatory information, automates submissions, and monitors expirations, standards, and regulations, helping companies get to market faster and reduce compliance risks.

To learn more or get a free demo, visit rimsys.io