

# Rimsys<sup>®</sup> | Case Study

## Omron Healthcare Mexico reduces time spent on regulatory reporting by 98%



### Products:

Heart monitoring equipment, blood pressure monitors, digital thermometers, and nebulizers

### Regulatory automation:

100 registrations for 50 products in 17 Latin America countries

Bi-weekly reporting on regional product registrations to corporate headquarters for production prioritization

### About Omron

Founded in 1933, Omron Healthcare is a leading global medical device manufacturer known for its heart monitoring equipment, blood pressure monitors, digital thermometers, and nebulizers. With a mission of improving the quality of healthcare through innovation, Omron sells its products in 110 countries and has sold hundreds of millions of products globally.

Omron Healthcare Mexico is responsible for managing regulatory activities for 17 countries in Latin America. Their regulatory team is small but committed to keeping the 50 products currently sold in the region on the market while also ensuring that new products get to market quickly.

### The problem: lack of standardization and regulatory information silos

As with many medtech organizations during the past couple of years, Omron Healthcare Mexico has seen a lot of organizational change. A combination of employee turnover, movement within the organization, and new role creation made regulatory continuity challenging. Not only was it difficult to fill employee knowledge gaps, but a lack of standardized processes across team members made finding regulatory information and collaboration across departments and office locations challenging.

Regulatory information was spread between multiple systems, including employee email, host files, and Microsoft SharePoint. Without a unified system in place, gathering and reporting regional product and registration information to Omron's corporate headquarters in Japan was often cumbersome and time-consuming.



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- Francisco Perez,  
Omron Healthcare Mexico



### **The solution:** a unified, automated approach to regulatory information management

The Omron team knew they needed a unified system for regulatory information to better maintain continuity amidst organizational changes, automate manual processes, and simplify collaboration across teams and locations. “Every person has a different view and a different way to manage information,” said Francisco Perez, a regulatory, quality, and customer service professional at Omron Healthcare Mexico. “When you can store regulatory information in a unified platform, it makes managing it and communicating change much easier.”

Omron Healthcare Mexico evaluated several RIM systems and ultimately chose Rimsys. As a part of the implementation process, Omron Healthcare Mexico’s regulatory team uploaded their products, registrations, and certificates in Rimsys. They began to see benefits quickly.

Rimsys has not only helped Omron organize and easily find registration information, but they can also more efficiently plan for new product launches. They set a new product’s registration status to “planned” in Rimsys and change the status once registration is complete and they have certificates available for that product. Having streamlined processes helps Omron onboard new team members much more easily and ensures that there are no regulatory gaps when they prepare to take new products to market.

Omron also saw cross-departmental benefits. Their product planning team responsible for conducting market research and connecting customers’ needs to products is now able to easily find the registration information it needs to ensure compliance and that product volume meets regional demands. “If our product planning team needs to check a registration, we don’t need to send an email. They can just log onto our platform and consult it,” said Francisco.

Instead of waiting for the RA team to manually pull the active registrations for their products, Omron’s sales team can now easily see where they can sell products within Rimsys. “If someone in Sales needs

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to see if we had an active registration or an active product, they can now easily check that information. They can use Rimsys to access the registration, download the certificate, and quickly share it.”

One of the biggest efficiencies Omron has gained from using Rimsys is with reporting. Omron Healthcare Mexico reports product information every two weeks to their Japan headquarters. This information is used to prioritize the production of their devices throughout Latin America based on active registrations, amendments, pending expirations, and renewals. “We have a really close relationship with our headquarters,” said Francisco. “The communications are really streamlined, and it’s important for them to know what we’re working on. Rimsys has helped us communicate our workload and which products we need to prioritize in our region.”

Reports that used to take the regulatory affairs team up to a couple of hours to complete now take 2 minutes, a time-savings of 98%. “We have 50 products on the market in the region and approximately 100 registrations. Without Rimsys, it would take us a lot longer to put these reports together,” says Francisco. Their headquarters office can directly access Omron Healthcare Mexico’s Registrations by Country report to get a holistic view of their products and registration status - allowing them to plan more efficiently, get additional products to this region faster, and drive more sales as a result.

### About Rimsys®

Rimsys is improving global health by accelerating delivery and increasing availability of life-changing medical technologies. Rimsys Regulatory Information Management (RIM) software helps medtech companies better manage regulatory projects and resources, get products to market more quickly, and ensure global regulatory compliance. Unlike complex spreadsheets or expensive consultants, Rimsys centralizes regulatory information, automates submission processes, and provides detailed visibility into product registrations, expirations, standards, and regulations.

To learn more or get a free demo, visit [rimsys.io](https://rimsys.io)