Rimsys® | Case Study

A leading dental adhesives manufacturer reduces essential principles & GSPR maintenance time by 99%

Products:

Dental adhesives & cement

Regulatory automation:

Registrations for 50+ product lines in 90+ countries

Digitization of 88 essential principles / GSPR tables for 3 regions

Starting as a family business, a leading global manufacturer of dental adhesives and cement has grown to sell over 50 different product lines in more than 90 countries around the world. Despite their growth, they remain mission-focused, with research, manufacturing, and marketing and sales teams co-located at their headquarters.

Regulatory affairs at the company is handled by a small, yet nimble team, who focus on ensuring that they have market clearance for all the countries where their products are sold. “I work with our product registrations and essential principles tables,” said their Global Regulatory Affairs Manager. “We have other team members who focus on working with our distributors and building and managing our technical docs.”

The situation: Lack of automation and poor process visibility

The regulatory affairs team was looking for a better way to manage registrations. While their registration information was well-organized, it was difficult to find and share. Registration documentation and certificates were stored in a central file system, with individual subfolders for each country and year. Regulatory submission assembly and information sharing with distributors was primarily handled through email communication and attachments.

Because the information was organized by country, it was difficult to search for individual products or documents, and email communication didn’t provide a lot of visibility into the process. “I wanted to make our registration processes less of a ‘black box’, and provide more visibility to our leadership team,” said their Global Regulatory Affairs Manager.

While registrations were the primary concern, the burden of maintaining essential principles tables was a growing problem as well. The pending Medical Device Regulations (MDR) in Europe added additional GSPR requirements and documentation scrutiny.

They also had to maintain essential principles for the ASEAN region. “Our EPs were 88 separate Word files held in our doc controls system,” said their Global Regulatory Affairs Manager, “Any time there was a change in a standard or an ISO cert we had to go in and manually edit each individual file. A few years ago, we had to do a large update to prepare for an audit. It took the whole team four days to make all the changes.”

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– Global RA Manager

The solution: Integrated regulatory information management

Looking to solve the challenges around product registrations, the regulatory affairs team initially looked at stand-alone regulatory intelligence and registration tools. However, as the team stepped back and examined all of their requirements, a broader solution that could help with registrations, essential principles, and document management was a better fit. The team selected the Rimsys RIM Platform to digitize and automate their regulatory activities. "We didn't know that RIM-type systems existed before working with Rimsys," said their Global Regulatory Affiars Manager, "But having everything in one place just makes sense. It gives us all the information at our fingertips in an easily searchable solution."

Working with the Rimsys implementation team, they were able to port all of their existing registrations, certificates, and individual SKU information into the Rimsys platform. To share and manage information with the existing document controls system, an integration was established with their RQMS system.

They also moved their essential principles documents for Europe, Australia, and ASEAN into the Rimsys RIM platform. This allowed them to automatically determine which essential principles were impacted by a standards change, and execute bulk updates across all of them.

Results: more efficient and effective regulatory affairs

Rimsys has helped their regulatory affairs team create registrations more quickly and streamline communication with their distributors. Rather than working through email, and manually pulling together documents, the team can assemble submissions in the system, and give distributors access to the relevant documents directly in the Rimsys platform. "We worked on a registration a couple of weeks ago where every document was in the system," said their Global Regulatory Affairs Manager, "That made it so much easier and faster for us."

The organization of information within the RIM system also made it much easier for the team to find information. "Before, everything was

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broken up by country and year, and it was much harder to search for things. Now we can go in by product and easily find previous registrations, or search for specific documents."

Rimsys has also greatly simplified the process of keeping essential principles tables up to date. Rather than sorting through multiple Word files to make updates, the team can make bulk updates across multiple tables to account for standards or certification changes. "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."

Moving forward, the team plans to expand Rimsys as a single source for all of their technical documentation, and open up more access to their distributors. The goal is to package all of the information a distributor needs—documents, registrations, essential principles, and allow them to access it directly in the platform.

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 regulatory affairs teams to plan more effectively, execute more quickly, and strengthen regulatory compliance by centralizing regulatory information, automating regulatory processes, and providing complete visibility into product registrations, expirations, and standards. With Rimsys, medtech companies can better manage regulatory projects and resources, get products to market faster , and reduce risk of non-compliance, product recalls, and unexpected expirations.

To learn more and see a demo, visit rimsys.io