Rimsys® Regulatory Management Software

CASE STUDY

EU IVDR GSPR Automation & Digitization

SITUATION

Discover how Rimsys digitized and automated the EU IVDR General Safety and Performance Requirements (GSPRs) for a global leader in the in-vitro diagnostics (IVD) market.

Rimsys implemented an off-the-shelf regulatory management software to digitalize the IVDR GSPR, necessary for compliance to the IVD Regulation (EU) 2017/746 of the European Parliament and of the Council. The software solution aimed to provide the global in-vitro diagnostics regulatory team with a more efficient and compliant means for creating and maintaining GSPR checklists for impacted products.

KEY DELIVERABLES

REDUCE

Compile external resources needed to update and maintain documentation, demonstrating IVDR compliance for GSPR documents

Eliminate non-value-added work for employees in regulatory, quality, and engineering groups

ACCESS

Achieve accurate and consistent updates for large batch changes to GSPR documents within a 21 CFR Part 11 compliant system

Utilize updated IVDR documentation for country registrations of global products and annual notified body audits

DIGITIZE

Automate application updates to GSPR documents when templates are updated

Enable efficient batch updating and batch approvals of changes to GSPR documents

Automate monitoring and communication of reference standards changes

SOLUTION

The Rimsys team worked directly with key customer stakeholders to fully understand and analyze their existing GSPR 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, create repeatable and scalable workflows, and maintain and bulk approve GSPRs

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.

RESULTS

1: DECREASED RELIANCE ON EXTERNAL RESOURCES TO BETTER ENABLE INTERNAL REGULATORY TEAM

Reduced 15 Consultants at Time of Go-Live

Eliminated High-Cost Consultant Expenses

Automated Administrative Work Duties

Kept Subject Matter Knowledge In-House

2: REDUCED NON-VALUE-ADDED WORK FOR REGULATORY, QUALITY, & ENGINEERING GROUPS

Reduced GSPR Time-to-Creation by 50%

Decreased Error Rate & Data Integrity Issues

Reduced GSPR Maintenance by 99%

Cut GSPR Update Process to < 30 Minutes

> *The company had 1,400 EU IVDR GSPRs and it took them three (3) weeks and three (3) regulatory professionals to update all of them when only one standard changed. Within Rimsys, it now takes one (1) employee less than 30 minutes to complete these updates!*

RESULTS

3: OBTAINED ACCURATE & CONSISTENT UPDATES FOR LARGE BATCH CHANGES TO GSPR DOCUMENTS

- Achieved Synchronized Update for 800 GSPRs
- Automated Notifications for Standard Updates
- Performed Bulk Updates to Files, Records, Etc.
- Reduced Human Error, Inconsistency, & Compliance Risks

4: ENABLED EFFICIENT BATCH UPDATING APPROVALS FOR CHANGES TO GSPR DOCUMENTS

- Reduced Hours & Resources for Admin Activities
- Eliminated Disparate Excel and Word Documents
- Removed Need for Week-Long, Manual Updates
- Achieved Batch Updates & Approvals in Minutes!

5: PROVIDED EASY ACCESS TO UPDATED IVDR DOCUMENTATION FOR COUNTRY REGISTRATIONS

- Updated Global Products & Annual Notified Body Audits
- Achieved Real-Time & Accessible Data Updates
- Implemented Auto-Generated GSPR Checklist
- Integrated Searchable & Compliant GSPR PDF

> *The auto-generated GSPR checklist is a searchable and compliant PDF that automatically includes the table of contents, page numbers, headers, footers, products, standards, evidence files, and additional information that met internal procedural requirements and external regulatory requirements.*

6: ENABLED AUTOMATIC UPDATES OF GSPR DOCUMENTS WHEN TEMPLATES CHANGED

- Automated Updates to GSPR Documents
- Ensured GSPR Documentation is Available & Current
- Provided Out-of-the-Box Templates
- Provided Custom Templates for Regional Jurisdictions

7: AUTOMATED MONITORING AND BULK UPDATES OF REFERENCE STANDARDS

- Automated Monitoring of Changed Standards
- Monitored 200+ Standard Developer Organizations
- Standards Are Associated to Product SKUs and GSPR
- Performed Bulk Updates to Global Documentation in Minutes

> *Rimsys is template-based for its GSPR solution and can make updates to existing templates that ensure the GSPR documentation is always available and current. Rimsys provides out-of-the-box templates that include the MDD/IVDD Essential Requirements, MDR/IVDR General Safety and Performance Requirements (GSPRs), TGA Essential Principles, and more.*

EXECUTIVE SUMMARY

When a global leader in the IVD market wanted to digitize the IVDR GSPR, Rimsys implemented its regulatory management software to provide the company with a more efficient means for accessing GSPR documents and batch changes. The software solution closed existing information gaps, automated manual processes and communication, and created repeatable workflows to mitigate regulatory risk and guarantee total compliance to the EU IVDR.

Rimsys® | Regulatory Management Software

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!

rimsys.io | letschat@rimsys.io | Follow us: