arena
A PTC BUSINESS

Rimsys Regulatory Management Software

ARENA-RIMSYS INTEGRATION

Simplify Medical Device Regulatory Management

OVERVIEW

Medical technology companies are finding it increasingly difficult to guarantee that products adhere to changing global regulations and need a solution for ensuring compliance. The seamless and deep integration between Arena and Rimsys ensures regulatory affairs professionals have access to the latest product and quality information.

The administrative burden of compiling marketing applications and the maintenance of product data is eliminated, allowing for increased compliance, efficiency, and visibility throughout the organization. Using this integrated solution, life sciences companies can address regulatory affairs, product registration, and standards management more easily and more effectively.

HOW IT WORKS

The Arena – Rimsys Integration ensures you have the latest, released product and quality documentation when compiling marketing applications, such as 510k, STED, and ToC. In addition, the integration imports records and documents from Arena to Rimsys for regulatory information, such as UDI requirements, standards management, essential principles, and marketing applications.

This integration:

- Imports new, released product and quality records from Arena into Rimsys
- Monitors product quality records and documentation in Arena for new, released revisions for import into Rimsys

BENEFITS

Reduce Time to Market

- A lot goes into getting a medical technology product to market. Efficiently sharing quality and engineering documentation with your regulatory management system shortens time to market, helps mitigate the price of the process, and brings organization that results in flexibility and compliance.

Improve Revenue

- Optimize your competitive edge and enjoy pricing benefits by hitting forecasted registration and product release dates consistently.

Comply With Global Regulations

- The global medical device industry requires compliance with regulations that vary by market. Regulators from different markets work together to identify instances of noncompliance and misalignment of information in submissions and other communications. Remaining in compliance with all regulations maintains your reputation around the world.

Collaborate

- Regulatory processes touch multiple functional areas. This solution connects product quality management and regulatory management to enable significant improvement. This solution enables the accurate and timely transfer of data and facilitates cross-functional workflows.

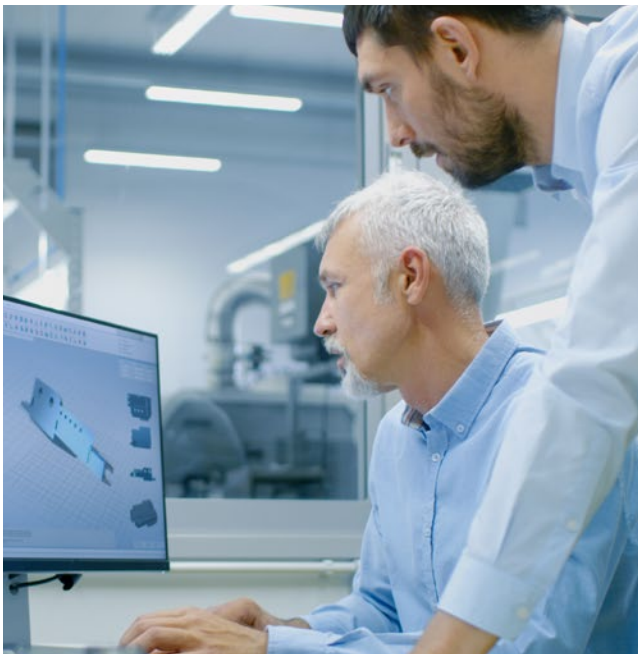
Engage Employees

- With access to the information they need, you empower your employees to resolve issues and help new employees come up to speed quickly.

- Product-Centric Global Registrations
- Submissions Management
- UDI (EUDAMED, GUDID)
- Marketing Authorizations (Selling Status)
- EU MDR/IVDR GSPR Automation

CAPABILITIES

- Rimsys seamlessly integrates with Arena by pulling quality records and documentation directly into Rimsys to create, manage, and maintain marketing applications such as 510(k)s, STEDs, ToCs, etc.
- The integration also monitors the quality records and documentation in Arena for any changes. Rimsys then alerts users and can run reports for all document locations ensuring a single source of truth.
- Rimsys integrates with Arena by syncing product data so companies can manage global registrations and selling status at the SKU level.



GETTING STARTED

It doesn't matter where you are in your journey with Arena and Rimsys — you can implement this no-code integration at any time. Live support is always available. Contact Arena or Rimsys sales to get started.

ABOUT ARENA

Arena, a PTC Business, helps companies create innovative products that change the world. Arena unifies product lifecycle management (PLM) and quality management system (QMS) processes, allowing every participant throughout product development and commercialization to work together fast and effectively. With Arena, dispersed teams accelerate the design and delivery of quality products. For more information, visit ArenaSolutions.com.

ABOUT RIMSYS

Rimsys is a 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. For more information, visit rimsys.io.