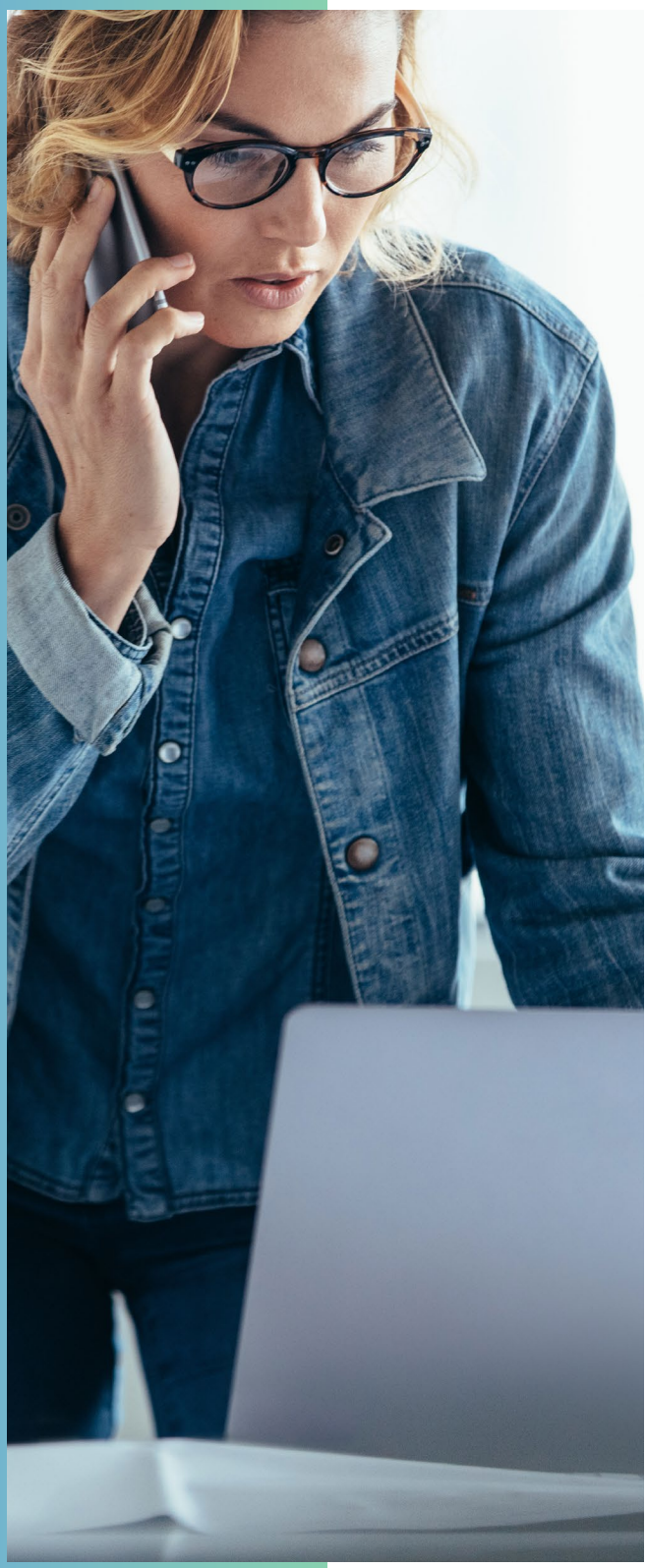
RAMS-TRACK:
Simplifying Medical Device Registration Tracking

May 2018



Managing device registrations and certificates typically involves labor-intensive, highly manual efforts from medical device manufacturers' Regulatory Affairs (RA) departments. Registration management entails four mission-critical elements:

- Tracking the regulatory status of a manufacturer's entire product line
- Becoming aware of the latest global medical device regulations
- Communicating crucial registration status notifications to key stakeholders and taking necessary action
- Determining when changes to a device require amendments to a registration, or applying for a new registration

RAMS-TRACK, a new web-based application, has been designed to help manufacturers manage and track their product registrations with ease. Using RAMS-TRACK, manufacturers' RA teams can stay on top of global regulatory trends impacting their registrations, as well as actively track registrations and certificates for entire product lines.

The RAMS-TRACK application provides companies a previously unavailable level of automation and insight to enable greater control and efficiency over medical device registration management. Furthermore, the application's automated alerting features help manufacturers reduce the risk of missing registration renewal deadlines, thereby avoiding significant setbacks to their commercialization plans.

RAMS-TRACK Benefits and Features

Avoiding registration expirations and regulatory oversights

RAMS-TRACK enables users to maintain registrations for devices already commercialized in various markets or for pending registrations submitted for products that are not yet approved. Using RAMS-TRACK alerts users to registrations that are set to expire, and helps keep users aware of the latest regulatory changes that may impact compliance requirements.

Once a RAMS-TRACK user has entered basic registration data into the application, it performs the following functions:

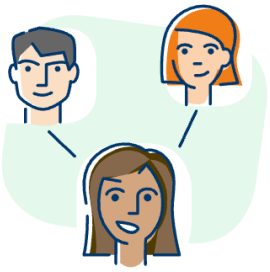
- Notifying users about upcoming registration expirations via in-application and email alerts
- Notifying users about new and upcoming regulatory changes that could impact their existing registrations and compliance
- Notifying users about the expirations of certificates that might affect the status of associated registrations
- Providing a registration renewal guide to inform users about the registration requirements for major medical device markets

Saving time

RAMS-TRACK reduces the historically manual and labor-intensive tasks necessary to manage and maintain device registrations, replacing those processes with an automated workflow. In particular, the application makes it easy to identify which registrations require attention or to find a particular registration based on specific search criteria. Importantly, manufacturers can get started with RAMS-TRACK quickly by importing their existing spreadsheets into RAMS-TRACK and re-purposing data they have previously compiled.

Gaining insights

RAMS-TRACK enables manufacturers to see the “big picture” of their registrations and product lines by providing automatically generated visual reports. For example, RAMS-TRACK’s expiration timeline helps manufacturers plan their resources by revealing when multiple registrations will need to be renewed in parallel. Similarly, RAMS-TRACK country reports visualize in which countries registrations will soon expire.



Collaborating easily and securely

RAMS-TRACK has been designed to facilitate collaboration among RA staff and their colleagues within and outside their organizations. Users can add an unlimited number of collaborators to their RAMS-TRACK accounts, and control whether collaborators can edit or only view registrations. Importantly, RAMS-TRACK maintains an audit trail of all edits to registrations, providing a clear history of all changes made to registration data.

Benefits for small and mid-sized manufacturers

Simplifying registration management processes yields distinct benefits for small and mid-sized versus larger medical device companies.

Smaller manufacturers typically have fewer RA resources to manage device registration application and renewal processes. And, often registrations are managed jointly with in-country representatives and local importers/distributors. Using RAMS-TRACK, these firms can monitor the regulatory status of their entire product lines and receive notifications when important regulatory deadlines are approaching, regardless of how limited their resources are.

Furthermore, RA personnel without extensive experience can utilize RAMS-TRACK tools to monitor regulatory developments in markets where their devices are registered to ensure ongoing compliance. In cases where regulatory changes in a particular market affect product registration requirements, RAMS-TRACK provides access to Emergo RA experts to support those efforts.

How RAMS-TRACK helps larger manufacturers

Larger medical device manufacturers tend to have more internal resources to allocate to RA processes, and usually rely less on outsourced support for these functions. For these companies, RAMS-TRACK helps address time-consuming, lower-level tasks, enabling RA staff to focus on the more mission-critical aspects of their roles.

For example, RAMS-TRACK provides automated tracking of device regulatory status, alerting users to upcoming expirations and informing them about upcoming spikes in the workload associated with registration renewals.

CASE STUDIES

Client 1: CooperSurgical, Inc.

CooperSurgical, based in Trumbull, CT, manufactures surgical devices, in vitro fertilization products, and medical products for use in a broad array of women's healthcare procedures. The company produces more than 200 families of medical products under multiple brand names, with offices across the US as well as in Europe and Costa Rica. The firm has more than 1,500 employees worldwide, and a Regulatory Affairs staff of 10. The firm supports product registrations/licensing for both direct sales and distributor sales worldwide.

CooperSurgical currently manages more than 1,000 medical device registrations across multiple markets.

Client 2: FujiFilm SonoSite, Inc. ("SonoSite")

FujiFilm SonoSite, Inc. ("SonoSite") with headquarters near Seattle, WA, specializes in developing, manufacturing and distributing multiple families of point-of-care ultrasound devices and technologies for use in point-of-care medical settings. The company utilizes multiple sales channels, including its own sales force as well as third-party distributors and strategic alliances across more than 80 markets worldwide.

SonoSite has 900 employees across the globe, including a small RA team that manages hundreds of device registrations.

Client 3: Mavig GmbH

Based in Munich, Germany, Mavig specializes in manufacturing X-Ray protection and medical suspension systems for use in institutional healthcare settings. The company has a portfolio of about 20 products, and manages roughly 100 medical device registrations worldwide. Mavig has 100 employees and a three-member RA team.

CooperSurgical, Inc.

The Challenge:

CooperSurgical's small RA department is challenged to manage a growing number of device registrations as the company acquired other manufacturers and incorporated their product lines into its own portfolio. In addition, RA staff members had to utilize limited resources to manage and communicate with a large and disparate network of international distributors.

The CooperSurgical RA department's use of manual device registration tracking via Excel spreadsheets created multiple problems and challenges:

- Inadequate control of data entry, resulting in incorrect and inconsistent information across different spreadsheets
- Difficulty finding information about specific device registrations either by product or country
- Document version control challenges such as identifying which spreadsheet contained most up-to-date registration information
- ***Missing registration renewal deadlines could result in lost revenue and additional regulatory compliance difficulties***

How RAMS-TRACK helped CooperSurgical:

Automated data control: By replacing their manual device registration tracking functions with RAMS-TRACK, CooperSurgical's RA team was able to begin storing information in a centralized, web-based application that gave them visibility into registration data for all marketed devices.

Enhanced accessibility: With RAMS-TRACK in place, the CooperSurgical RA team controls who has access to add or edit registration information in the system. Users also have the ability to add accounts for distributors into RAMS-TRACK; a distributor may access only registrations it holds, not those associated with other distributors.

Improved auditing: In terms of improved data management, RAMS-TRACK has enabled the CooperSurgical RA team to organize registration information more consistently, and provides autocomplete functionality to reduce data entry errors and produce higher-quality registration data. Using RAMS-TRACK's built-in audit trail capability, the RA team can now review all edits and renewals made to registration files, as well.

Reduced operational risk: To avoid missed registration renewal deadlines, CooperSurgical receives expiration alerts from the RAMS-TRACK system that notify RA staff when renewal deadlines are approaching. Alerts may be set per country or market to allow CooperSurgical adequate time to address regulatory renewal requirements and ensure ongoing compliance.

FujiFilm SonoSite, Inc.

The Challenge:

The SonoSite RA team's use of manual Excel spreadsheets along with the high degree of configurability of the company's products has led to challenges maintaining registration and compliance data.

- **Configurability:** SonoSite devices may be configured in various ways, creating numerous combinations of devices, software and accessories whose registration details must all be tracked in spreadsheets
- ***Reporting: When the RA team receives requests from management for product distribution reports, they must manually prepare that documentation by extracting data from various spreadsheets***
- **Multiple markets:** Because SonoSite devices are sold in more than 80 countries, the RA team faced difficulties in tracking and maintaining regulatory paperwork for each market where devices are registered
- **Manual processes:** Excel spreadsheets offer little support for monitoring different registration renewal timeframes across various markets where SonoSite devices are sold, or for sharing registration data with other RA team members or departments

How RAMS-TRACK Helped SonoSite:

Interface: RAMS-TRACK's user interface design and navigation features enable RA staff to enter and retrieve data on multiple SonoSite product configurations.

Report building: RAMS-TRACK automatically generates graphical reports that provide an overview of registrations according to expiration dates, country, product, or status, eliminating the need to manually prepare reports for management.

Registration alerts: RAMS-TRACK regulatory alerts notify RA team members when regulatory changes in a specific market may impact one or more of SonoSite's device registrations.

Data sharing: RAMS-TRACK allows users to quickly share registration data both internally and with other departments via email, PDF or Excel documents. RA staff can also attach licenses, certificates, and other associated documentation to individual registration files, making it easy for staff to find important details when reviewing registrations or preparing renewals.

Mavig GmbH

The Challenge:

Due to limited, highly manual internal RA resources, Mavig faced challenges maintaining its product registrations and training new staff to manage ongoing regulatory compliance efforts.

- **Training:** Mavig had to train new RA team members quickly on the firm's current roster of device registrations
- ***Document management:** RA staff were challenged to find registration documents, and to identify and keep up with medical device regulatory requirements and changes to requirements in multiple markets*
- **Resource management:** Mavig's RA staff had difficulty estimating the amount of internal resources needed to keep up with product registration renewal activities

How RAMS-TRACK Helped MAVIG:

Centralized data resources: Using RAMS-TRACK, Mavig RA staff now have a centralized repository of registration data available to the department. In addition, RAMS-TRACK users can quickly and easily attach certificates and related documentation to individual registration records, cutting down on time required to locate and compile requested information.

Recordkeeping efficiencies: RAMS-TRACK's audit trail capabilities allow Mavig users to build clear histories of edits and renewals of individual registrations. Plus, the system's in-built registration renewal guide provides overviews of registration requirements for major medical device markets, allowing new RA staff members to understand and prioritize registration renewal processes.