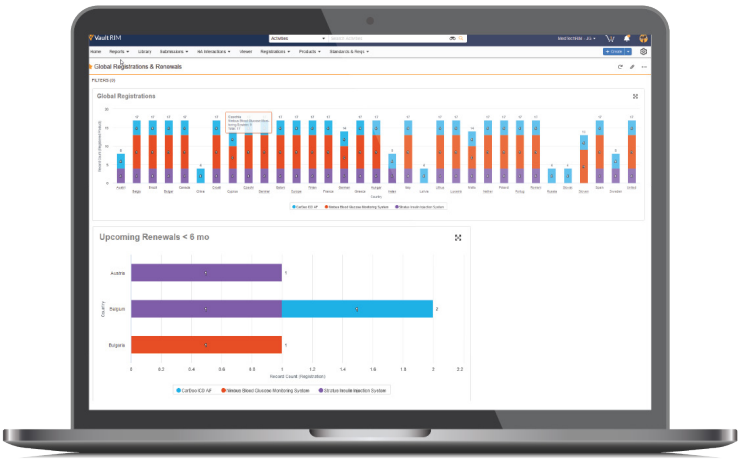
Registrations

Global product registrations, health authority interactions, and commitments



In many organizations, regulatory teams track global product registrations in multiple spreadsheets or across siloed legacy tools with limited accessibility. Headquarters struggles with poor visibility into affiliate operations and health authority interactions, requiring manual product status aggregations, often resulting in delays and data discrepancies.

Veeva Registrations streamlines planning, tracking, and reporting of global product registrations and health authority interactions on a single platform. It provides tools that help teams quickly assess the impact of manufacturing or labeling changes so they can make data-driven decisions throughout the product lifecycle.

Veeva Registrations helps companies capture the information they need to meet global regulations like EU MDR/IVDR and UDI requirements. Veeva is committed to adding data fields, enabling new features, and sourcing information through its open API to support customers as standards evolve.

Benefits

Better visibility: Leverage complete product information for better global strategic decision-making, registration tracking, and health authority interactions.

More efficient registration process: Reduce rework, respond faster to market changes, and spend less time searching for up-to-date information.

Trusted compliance: Ensure accurate data to seamlessly meet global regulatory requirements.

Unified RIM: Connect end-to-end regulatory processes and improve efficiency as part of the Veeva RIM Platform.

Features

Global Product Registrations

Manage registration information for marketed products and investigational devices including unique device identifiers (UDIs), nomenclature codes, intended uses, packaging specifics, and manufacturing details. Manage license updates and renewals and report on the latest approved details.

Health Authority Interactions

Retain and classify all correspondence with health authorities. Track questions from health authorities as well as plan and author responses to questions. Also, track commitments to health authorities and related meetings.

Change Management

Plan and track proposed changes to global registrations. Assess the impact of a proposed change and delegate actions to local affiliates to execute the change in their market. Bundle changes together or split them apart according to your regulatory strategy. Optionally, leverage a seamless connection with **Veeva QMS** to automate the creation of any planned change triggered by your quality change control process.

UDI Support

Manage the lifecycle of UDI data for your devices with a harmonized approach for EU, US, and other markets. Validate and submit UDI data electronically to EUDAMED.

Dashboards and Reports

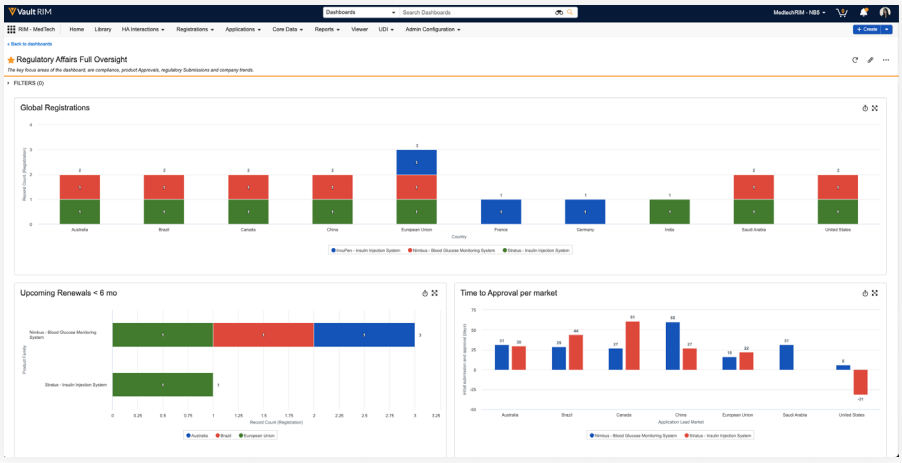
Create easy, self-serve reports showing information by any combination of attributes including product, application, region, manufacturer, and more. Address any bottlenecks or delays by re-assigning tasks or sending reminders directly from within the report.

Affiliate Home Page

Encourage local user adoption with a specific user interface that allows market product owners to view all country-specific data points in a simple graphic format with quick-launch buttons to update local data.

Global Content Plans

Centrally assemble global or core documents related to a multi-market change for streamlined content reuse across local submissions, including those with varying submission structures.



Veeva RIM Platform

Veeva Registrations is part of the **Veeva RIM Platform**, which streamlines global regulatory processes on a single, cloud-based platform. This enables medtech companies to:

- Ensure teams are developing reliable regulatory content with high data integrity
- Coordinate regulatory efforts across headquarters, affiliates, and partners
- Respond faster to changing regulations
- Increase end-to-end process efficiency from submission planning to publishing