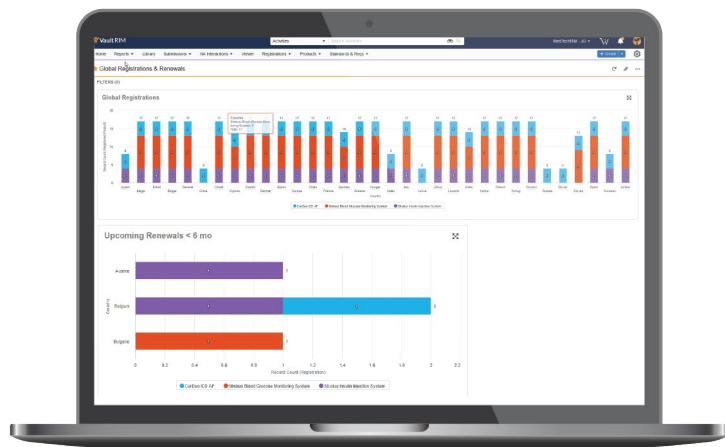


Vault Registrations

Global product registrations, health authority interactions, and commitments

In many organizations, regulatory teams track product registrations on multiple spreadsheets or in complex legacy tools that are not globally accessible. Headquarters often lacks visibility into local affiliate operations and health authority interactions, so it must manually aggregate product status information, which can cause delays and introduce data discrepancies.



Veeva Vault Registrations enables companies to plan, track, and report on global product registrations and health authority correspondence and commitments within a single system. It includes powerful tools to help teams quickly assess the impact of manufacturing or labeling changes so they can make more informed decisions throughout the product lifecycle.

With a flexible data model, Vault Registrations also helps companies capture the information they need to meet global regulations like EU MDR/IVDR, US, or other global UDI regulations. As regulations continue to evolve, Veeva is committed to adding data fields, enabling new features, and pulling in information through its open API to support customers and provide resilience over time.

Benefits

- **Improved data quality:** Streamline registration management by reducing data duplicates and discrepancies.
- **Global visibility:** Stay informed with complete visibility into the marketing status of your global product portfolio.
- **Faster responses to health authorities:** Track product registration queries and commitments to stay ahead of response deadlines.
- **Unified RIM:** Connect end-to-end regulatory processes and improve efficiency as part of the Veeva Vault RIM Platform.

Features

Global Product Registrations

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

Health Authority Interactions and Commitments

Retain and classify all correspondence with health authorities. Create commitment records with related tasks and report on progress against outstanding commitments and deliverables.

Change Management

Track proposed changes to global registrations. Determine the impact of a proposed change and delegate actions to local affiliates to execute the change in their market. Optionally, leverage a seamless connection with **Veeva Vault QMS** to automate the creation of any planned change triggered by your quality change control process.

UDI Support

Capture the data needed for day-to-day operations and to utilize that data in different ways. Be ready to publish data in multiple formats, such as EU MDR/IVDR, US, or other global UDI regulations.

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 (pictured below).

The screenshot displays the Veeva Vault RIM Platform interface. The top navigation bar includes 'Home', 'Reports', 'Library', 'Submissions', 'HA Interactions', 'Viewer', 'Registrations' (selected), 'Products', and 'Standards & Recs'. A search bar is present next to the 'Registrations' tab. The main content area shows a table titled 'All Registrations' with columns: Name, Country, Registration Start Date, Registration End Date, and Marketing Start Date. The table lists various medical devices and systems across different countries, including Austria, Belgium, Bulgaria, France, Mexico, Brazil, and Canada. The interface also includes a left sidebar with filters for 'All Registrations', 'Recent Registrations', 'Favorites', 'All Registrations ending 180 days', 'All Registrations ending 180 days', 'Manufacturers', 'Status', 'PRODUCT FAMILY', 'REGISTRATION END DATE', and 'COUNTRY'.

Name	Country	Registration Start Date	Registration End Date	Marketing Start Date
AT - CarDex ICD AF	Austria	06 May 2016	27 May 2026	15 Jun 2016
AT - Nimbus Blood Glucose Monitoring System	Austria			
AT - Status Insulin Injection System	Austria	08 Nov 2016	08 Nov 2021	13 Oct 2016
BE - CarDex ICD AF	Belgium	15 Apr 2018	08 Nov 2021	15 Jun 2018
BE - Nimbus Blood Glucose Monitoring System	Belgium			
BE - Status Insulin Injection System	Belgium	03 Nov 2017	03 Nov 2021	13 Oct 2017
BG - CarDex ICD AF	Bulgaria	15 Apr 2018	15 Apr 2023	15 Jun 2018
BG - Nimbus Blood Glucose Monitoring System	Bulgaria	03 Nov 2016	03 Nov 2021	
BG - Status Insulin Injection System	Bulgaria	06 Apr 2016	06 Apr 2026	05 Mar 2016
FR - CarDex ICD AF	France	15 Apr 2018	15 Apr 2023	15 Jun 2018
MX - Nimbus Blood Glucose Monitoring System	Mexico			
BR - Status Insulin Injection System	Brazil	06 Apr 2016	06 Apr 2026	05 Mar 2016
CA - CarDex ICD AF	Canada	15 Apr 2018	15 Apr 2023	15 Jun 2018
CA - Nimbus Blood Glucose Monitoring System	Canada			
CA - Status Insulin Injection System	Canada	06 Apr 2016	06 Apr 2026	05 Mar 2016

Veeva Vault RIM Platform

Vault Registrations is part of the **Veeva Vault 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