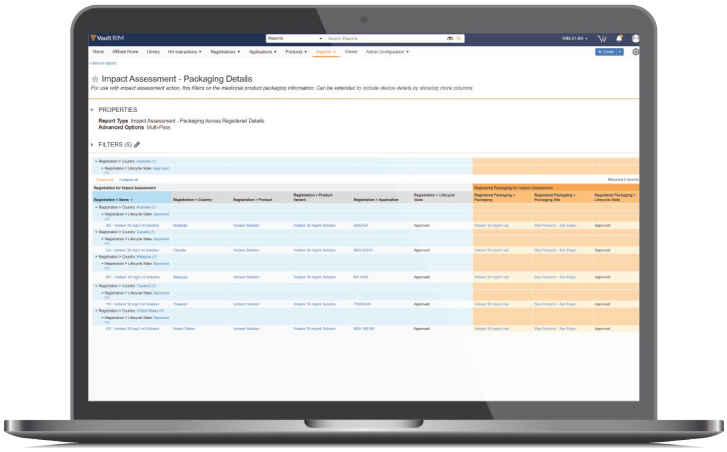
Veeva Vault Registrations

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 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 XEVMPD and IDMP. As standards 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 all marketing and investigational registration information, including packaging specifics, indications, and manufacturing details. Manage updates to registered data and report on 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.

Variation 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.

Product Data Snapshots

Generate XEVMPD data snapshots from your latest registration data, allowing manual overrides, generation of health authority required output, and bi-directional communication via health authority gateways.

XEVMPD and IDMP Support

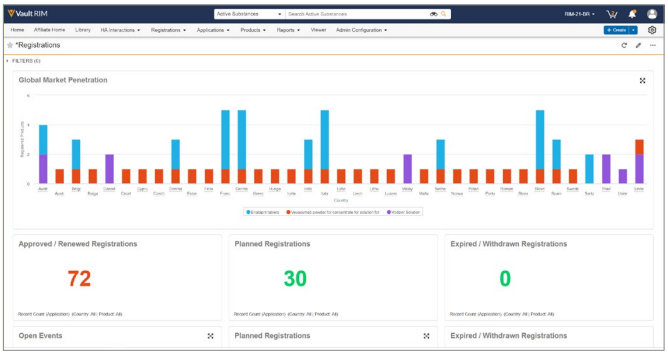
Accommodate XEVMPD and IDMP source data points in the context of regulatory data management and pull in information from other systems through Vault's open API.

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).



Active Dossier

Maintain a list of current documents for a given product and market. Automatically populate the correct structure for a given submission, calculate the current status for a regulatory objective and its related submissions, and gain access to relevant translation source files.

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 life sciences 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