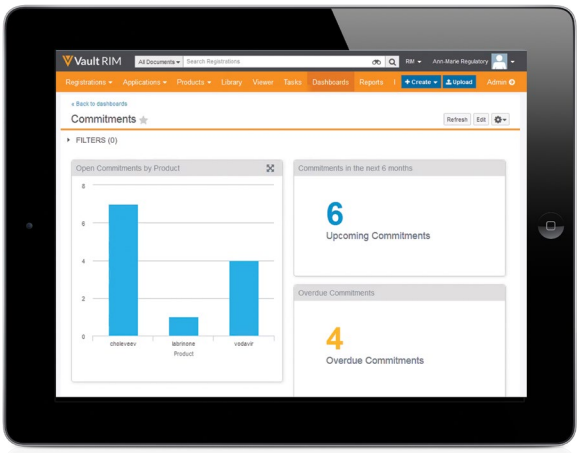
Datasheet

Veeva Vault Registrations



A single global application for managing product registrations, health authority correspondence, and commitments.

In many organizations, registration tracking is done on multiple spreadsheets or in complex legacy tools that are not globally accessible. Headquarters often lacks visibility into affiliate operations and must aggregate status information manually.

Veeva Vault Registrations allows companies to manage registration information and health authority interactions for their entire product portfolio, helping regulatory teams gain control over resources and activities around the globe. With Vault's advanced planning, workflow, and tracking capabilities, organizations can proactively manage registrations and regulatory events throughout the product lifecycle of variations, amendments, and renewals.

As a shared resource for headquarters, affiliates, and partners, Vault Registrations provides visibility across the organization, enabling regulatory teams to make informed decisions faster.

Benefits

- **Global visibility:** Stay informed with complete visibility into the marketing status of your global product portfolio.
- **Improved data quality:** Streamline registration management by reducing data duplicates and discrepancies.
- **Increased agility:** Quickly assess the global impact of events such as manufacturing or label changes.
- **Faster responses to health authorities:** Track queries and commitments to stay ahead of response deadlines.

IDMP and XEVMPD Support

Vault Registrations provides support for evolving regulatory data standards through our advanced data model. We accommodate IDMP data points in the context of regulatory data management and pull in information from other systems through Vault's open application programming interface (API). This gives our customers more flexibility and resilience over time.

Veeva Vault Registrations

Features

Global Product Registrations

Manage all product registration details, including formulation specifics, modes of delivery and dosage forms, indications, manufacturing details, and packaging.

Impact Analysis Reports

Generate reports to identify which registrations are impacted by a potential change, and then kick off the process to respond.

Task Creation and Assignments

Build a plan for and manage your response to regulatory events by creating the associated activities and assigning responsible parties.

Submission Planning

Plan, manage, and track the status of submissions and related activities. This includes data related to initial clinical trial or marketing submissions.

Interactions and Commitments

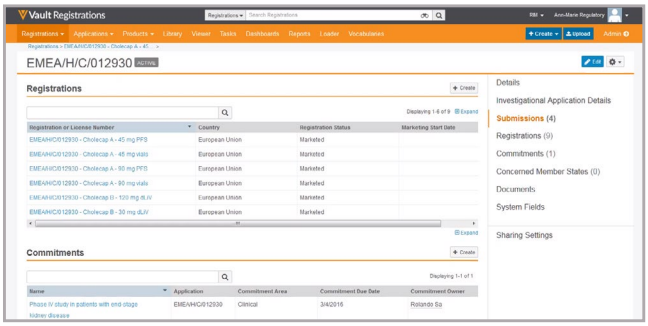
Retain and classify all correspondence with health authorities. Create commitment records with related tasks and report on progress against outstanding commitments and deliverables.

Dashboards and Reports

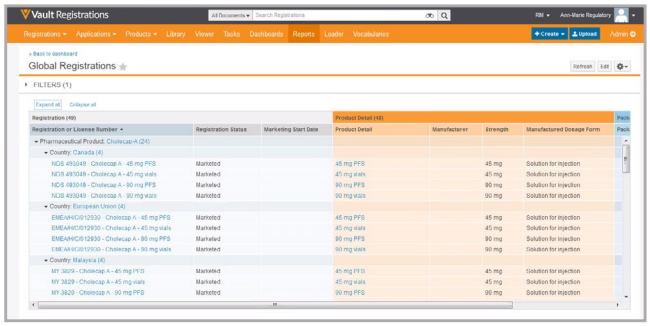
Create easy, self-serve reports showing information by any combination of attributes, including product, application, region, manufacturer, and more. Address any bottlenecks or delays by re-assigning tasks or sending reminders directly from within the report.

Open Programming Interface

Integrate with business systems outside of regulatory to streamline the exchange of data with other departments and external systems.



Gain a holistic view of your application with registrations, commitments, and submission status on a single, intuitive page.



Move directly from insight to action with interactive dashboards and reports.

Veeva Vault RIM Suite

Veeva Vault RIM Suite unifies regulatory information management (RIM) capabilities on a single cloud-based platform for managing product registrations, product data reporting, submission documents, publishing, health authority correspondence and commitments, and archived dossiers.

In today's fragmented RIM environment, with separate tools for each function and different systems in each region, it is challenging for organizations to respond quickly to regulatory events or information requests. Veeva's unified RIM suite delivers the data quality, visibility, and global alignment needed to transform regulatory processes. Only with a unified RIM solution can companies become more agile and maximize the value of their product portfolio.