Vault RIM Suite

An Authoritative Source for Regulatory Information Management (RIM)

Uniting Registration Data, Submissions Documents, and Archived Submissions

For most MedTech companies, coordinating regulatory activities worldwide creates several challenges. Companies struggle with poor data quality, duplication, and limited visibility into regulatory activities as a result of disjointed processes and a myriad of tools for each regulatory task. Reducing this complexity is a critical step to streamline compliance processes in global markets.

Veeva MedTech now includes regulatory applications, which provide an authoritative source for regulatory documents and information globally. Content and data converge in a single cloud platform to unify registration tracking, correspondence and commitments, submission document management, and regulatory submissions archiving.

A single authoritative source makes work more efficient. Data and documents are entered just once and are accessible in any context. This approach minimizes discrepancies and uncontrolled copies, ensuring your information is accurate, timely, and accessible. Organizations can respond faster to product changes, compliance concerns, or health authority requests.

Benefits

- **Speed to market globally:** Respond faster to business changes by quickly assessing the impact of proposed changes, locating source documents, and coordinating activities globally.
- **Reliable data quality:** Capture timely, accurate information directly from each region and share it globally to eliminate data duplication and discrepancies.
- **Global alignment:** Gain visibility across headquarters, affiliate, and partner activities.
- **Always current:** Receive new functionality three times a year to keep you current with technology advances and emerging regulatory requirements.

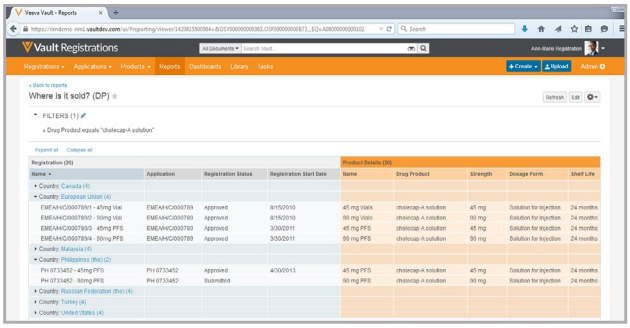

Figure 1. Personalize views and reports by product, country, status, and more.

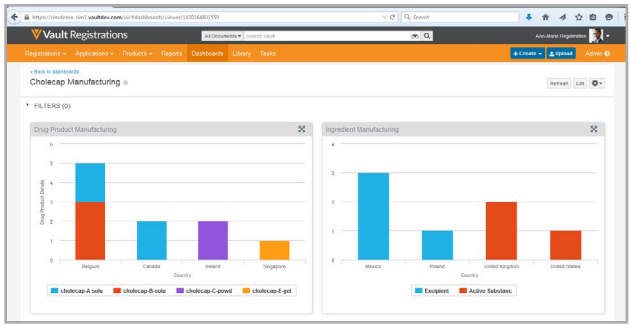

Figure 2. Easily find where products are manufactured or sold.

Vault Registrations

Vault Registrations provides a single, comprehensive solution to manage product registration data worldwide, license changes and renewals, and health authority interactions. Companies can manage registration information such as approved product variants, packaging configurations, and systems configurations across all global markets. Medical device product registration data is modeled to conform with US and EU UDI guidelines. As a shared resource for headquarters and affiliates, Vault Registrations helps globalize key processes and improve data quality.

Vault Submissions

Vault Submissions manages the authoring, planning, collection, and approval of documents for submission to regulatory authorities. Vault Submissions supports industry-standard content formats such as STED and the IMDRF Table of Contents as well as market-specific formats like 510(k) to ensure that the content taxonomy aligns with industry norms and facilitates collaboration with external parties. Submission content plans show you expected documents and track submission completeness in real-time without manual updates. Templates and placeholders assist with the creation and collection of required materials, while Vault's reporting and approval workflows ensure necessary documents are included and complete.

Vault Submissions Archive

Vault Submissions Archive stores your complete history of regulatory submissions securely in the cloud. A high-performance cloud architecture makes access to published submissions fast and easy. Affiliates can download submissions or submission components for reuse in local markets. Vault Submissions Archive imports submissions directly from file shares while preserving the folder structure and inter-document hyperlinks. Users can navigate documents exactly as they were submitted to regulatory agencies and directly from the repository without downloading files.