Datasheet

Veeva Vault RIM

An Authoritative Source for Regulatory Information Management (RIM)

Uniting Registration Data, Submissions Documents, and Published Dossiers

For most life sciences companies, coordinating regulatory activities worldwide has never been easy. 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.

The Vault RIM suite of applications provides 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

Always current: Veeva adds new functionality three times a year to keep you current with technology and emerging regulatory requirements. You can concentrate on your business, rather than system upgrades and custom IT development.

High productivity: The Vault cloud platform delivers fast performance to your users all around the world. Powerful search and consumer web ease of use lower training requirements and result in higher and more frequent use of the system.

Reliable data quality: Capture timely, accurate information directly from each region and share it globally to eliminate data duplication and discrepancies.

Agile and integrated: Leverage Vault's powerful platform capabilities to quickly configure new data types and workflows, integrate with other regulatory systems, and quickly write the reports you need to keep processes moving.

Veeva Vault RIM

Affiliate Friendly

Vault is easily accessed by headquarters, affiliates, distributors, or outsourcing partners. Each party sees a tailored view of the information they care about most. Affiliates can add local information to the global system and headquarters can easily share critical data and documents directly with the affiliates.

Real-time Visibility

It is critical to know where your products are registered, what commitments are outstanding, and which registrations would be impacted by a potential manufacturing change. Vault's real-time reporting and dashboards help answer questions about registration status and submission readiness.

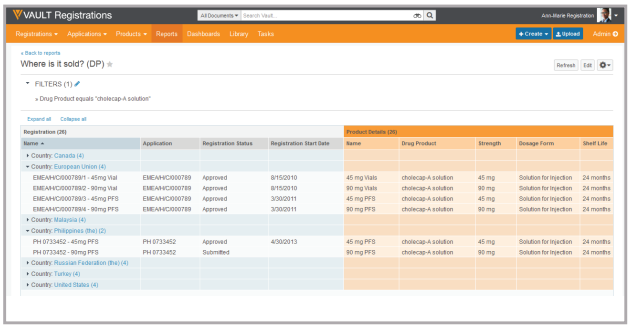

Figure 1. Personalize views and reports by product, country, status, and more.

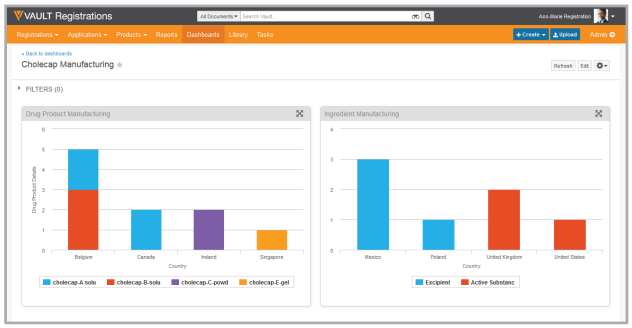

Figure 2. Easily find where products are manufactured or sold.

Vault Registrations

Veeva Vault Registrations provides a single, comprehensive solution to manage product registration data worldwide, including registration status, variations, and health authority interactions.

Companies can manage registration information such as approved pack sizes, dosage forms, and strengths across all global markets. As a shared resource for headquarters and affiliates, Vault Registrations helps globalize key processes and improve data quality.

Vault Registrations also provides IDMP support. The application can receive data from external systems and will generate IDMP messages. Vault Registration's flexible data model natively maps to the IDMP standard and can incorporate future updates.

Vault Submissions

Veeva Vault Submissions manages the authoring, planning, collection, and approval of documents for submission to regulatory authorities.

Vault supports and extends the DIA Reference Model to ensure that the content taxonomy aligns with industry norms and facilitates collaboration with external parties. Submission templates automatically generate a "bill of materials" that lists required documents, so it's instantly clear what's missing. Then, document 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 SubmissionsArchive

Veeva Vault SubmissionsArchive will store 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 SubmissionsArchive will allow you to import submissions directly from file shares while preserving the eCTD XML backbone, 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. An integrated viewer provides current, sequential, and regulatory action views so users can quickly navigate published dossiers.