Datasheet

Veeva Vault RIM Suite

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 Veeva 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, dossier publishing, 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.

Veeva Vault RIM Suite

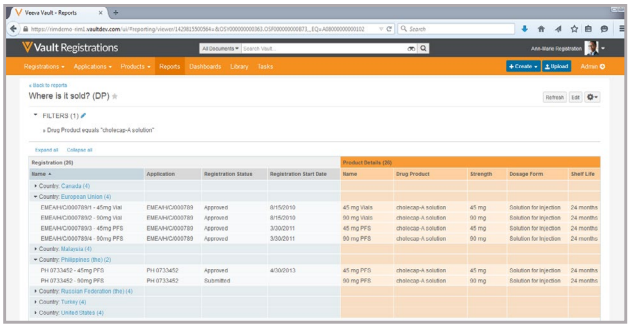

Figure 1. Personalize views and reports by product, country, status, and more.

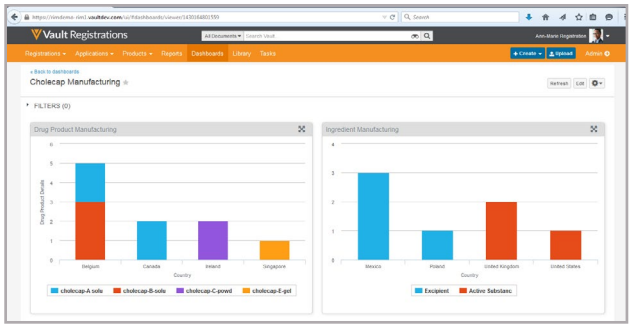

Figure 2. Easily find where products are manufactured or sold.

Vault Registrations

Vault Registrations provides a single, comprehensive solution to manage product registration data worldwide, 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 Registrations' flexible data model natively maps to the IDMP standard and can incorporate future updates.

Vault Submissions

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

Vault Submissions supports and extends the DIA Reference Model 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 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 eCTD viewer provides current, sequential, cumulative, and regulatory action views so users can quickly navigate published dossiers.

Vault Submissions Publishing

Vault Submissions Publishing seamlessly incorporates publishing capabilities within the Vault RIM Suite. Veeva's unified RIM approach moves cross-document hyperlinking and link-testing upstream during authoring and reviews. Validations and XML generation are done behind-the-scenes and as you go, so issues are identified earlier when they are easier to fix. Shifting publishing work upstream reduces time pressure during submission crunch time.

By unifying the end-to-end process, Vault Submissions Publishing can provide innovative capabilities such as submission-independent hyperlinking and assisted submission building. The continuous publishing process within Veeva Vault RIM offers greater automation, transparency, and speed.