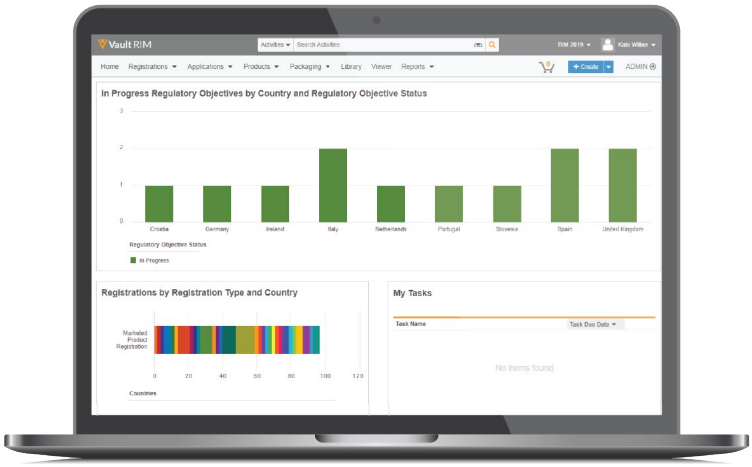
Datasheet

Veeva Vault RIM Suite

End-to-end RIM on a unified platform



For most life sciences companies, coordinating regulatory information management (RIM) activities worldwide is incredibly complex. Companies struggle with poor data quality, duplication, and visibility due to 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 that unifies registration tracking, correspondence and commitments, submission document management, dossier publishing, and regulatory submission 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. With a unified Vault RIM Suite that streamlines end-to-end regulatory processes, organizations can respond faster to product changes, compliance concerns, and 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.
- **Stronger compliance:** Ensure teams are developing reliable regulatory content with high data integrity.
- **Global alignment:** Coordinate regulatory efforts across HQ, affiliates, and partners within a single RIM system.
- **Unified and connected:** Streamline cross-functional business processes that involve clinical, quality, and safety teams with the Veeva Development Cloud.

Vault Registrations

Vault Registrations provides a single system to plan, track, and report on global product registrations and health authority correspondence and commitments. Companies can manage all marketing and investigational registration information including packaging specifics, indications, and manufacturing details as well as updates to registered data. Vault Registrations includes powerful tools to help teams quickly assess the impact of manufacturing or label 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.

Vault Submissions Publishing

Vault Submissions Publishing seamlessly incorporates capabilities within the Vault RIM Suite to provide a continuous publishing process that dramatically speeds submission delivery. Now regulatory teams can perform cross-document hyperlinking and validation earlier in the process when issues are easier to fix. Vault Submissions Publishing is used in conjunction with Vault Submissions and Vault Submissions Archive to streamline the end-to-end publishing process and drive greater automation, transparency, and speed.

Vault Submissions

Vault Submissions eliminates the need for multiple, disparate tracking systems by providing a single, authoritative source for regulatory submissions content - all in a secure cloud environment. Companies can manage the entire submission lifecycle from planning to authoring to assembly and gain greater access, visibility, and control over their documents and data. Vault Submissions also allows content creators to securely access and contribute to documents from any location, at any time, and on any device. Users can cross-link documents to source materials such as clinical documents, manufacturing details, SOPs, and promotional materials and see visual reminders of outstanding tasks. This enables each department to manage content within their own context, while maintaining a single source of truth across the organization.

Vault Submissions Archive

Vault Submissions Archive stores eCTD and non-eCTD electronic submissions with links to related health authority correspondence. Affiliates can download submissions or submission components for reuse in local markets and upload submissions already sent to various health authorities. Vault Submissions Archive also enables companies 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 needing to download files. An integrated eCTD viewer provides current, sequential, cumulative, and regulatory action views so users can quickly see the full lifecycle of an application.

How Vault Empowers Organizations of All Sizes

- An intuitive interface and reliably high performance makes Vault easy to navigate with minimal training
- Predefined distribution workflows ensure activities are compliant with SOPs
- Affiliate-specific views, searches, and reports help users understand what content exists, what state it's in, and where it has been used so they can quickly answer questions about progress and readiness
- Flexible data models and security accommodate local variations to enable system consolidation
- A cloud-based architecture means there are no servers to buy or maintain, no software upgrade projects, and system validation costs are dramatically reduced