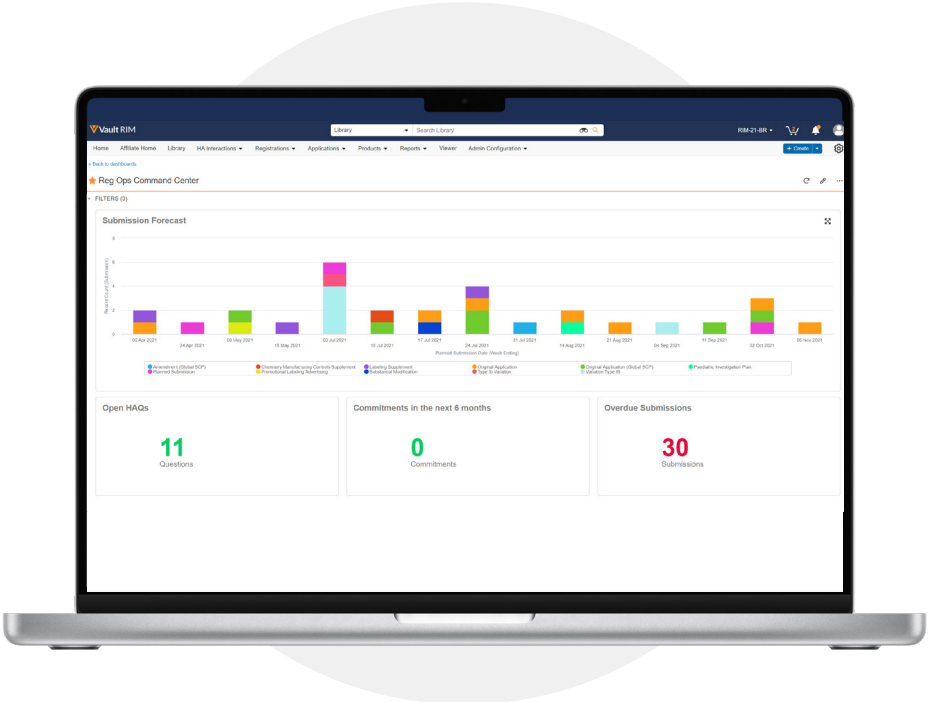
# End-to-end RIM on a unified platform

For most life sciences companies, coordinating regulatory information management (RIM) activities across global markets is incredibly complex. Companies struggle with poor data quality, inefficient collaboration, and limited visibility due to disjointed processes and siloed systems. Streamlining these operations is critical for accelerating product time to market while remaining compliant.

Veeva RIM provides an authoritative source for regulatory documents and information globally. Content and data are managed in a single cloud platform for unified registration tracking, health authority interactions, submission document management, dossier publishing, and regulatory submission archiving.

A unified solution helps reduce duplicative efforts while improving data quality through automation that leverages existing system records. It also enables global teams to collaborate in real time on a single platform. Veeva RIM improves end-to-end regulatory process efficiency, enabling faster responses to product changes, compliance concerns, and health authority requests.



## Business Benefits

**Accelerate speed to market.**

Faster submission assembly and publishing through increased visibility and collaboration.

**Automated compliance updates.**

Adapt seamlessly to evolving global regulatory requirements with automated updates.

**Real time data-driven decisions.**

Enable data-driven decisions across all steps of the submission lifecycle.

**Unified and connected.**

Streamline cross-functional business processes that involve clinical, quality, and safety teams.

## Platform Features

### Health Authority Interactions

Retain and classify all correspondence with health authorities. Extract and track questions from health authorities as well as plan and author responses to questions. Also, track commitments to health authorities and related meetings.

### Active Dossier

Maintain and visualize a holistic list of current and upcoming approved documents for a given product and market. Automate based on submission management processes and gain quick traceability to the relevant submission details and document links in one place.

### Global Content Plans

Centrally assemble global or core documents related to a multi-market change for streamlined content reuse across local submissions, including those with varying submission structures.

### Dashboards and Reports

Create self-serve reports that show historic submissions by any combination of attributes including product, submission type, country, manufacturer, and more.

# Applications

## Veeva Registrations

Veeva Registrations provides a single system to plan, track, and report on global product registrations. Companies can manage all marketing and investigational registration information including packaging specifics, indications, and manufacturing details as well as updates to registered data. Veeva Registrations includes tools to help teams quickly assess the impact of manufacturing or label changes so they can make data-driven decisions throughout the product lifecycle. Veeva Registrations also helps companies capture the information they need to meet global regulations like XEVMPD and IDMP.

## Veeva Submissions

Veeva Submissions eliminates the need for multiple, disparate tracking systems by providing a single, authoritative source for regulatory submissions content in a secure cloud environment. Companies can manage the entire submission lifecycle from planning to authoring and assembly for greater access, visibility, and control over their documents and data. Veeva Submissions allows content creators to securely access and contribute to documents from any location, at any time, and on any device. Users can reference source materials from other applications, such as clinical documents, manufacturing details, SOPs, and promotional materials. This enables each department to manage content within their own context while maintaining a single source of truth across the organization. With Registrations, core documents for multi-market changes can be assembled at the global level and bulk dispatched to multiple target submissions.

## Veeva Submissions Publishing

Veeva Submissions Publishing seamlessly incorporates continuous publishing within Veeva RIM to dramatically speed submission delivery. Now regulatory teams can perform cross-document hyperlinking and validation earlier in the process when issues are easier to fix. Veeva Submissions Publishing is used in conjunction with Veeva Submissions and Veeva Submissions Archive to streamline the end-to-end publishing process from submission creation to gateway delivery, driving greater automation, transparency, and speed.

## Veeva Submissions Archive

Veeva Submissions Archive stores eCTD and non-eCTD electronic submissions as well as displays related health authority correspondence. Affiliates can download submissions for reuse in local markets and import submissions already sent to various health authorities. Veeva Submissions Archive enables organizations to import submissions directly from file shares while preserving the eCTD XML backbone, folder structure, and relative 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
- Configurable 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