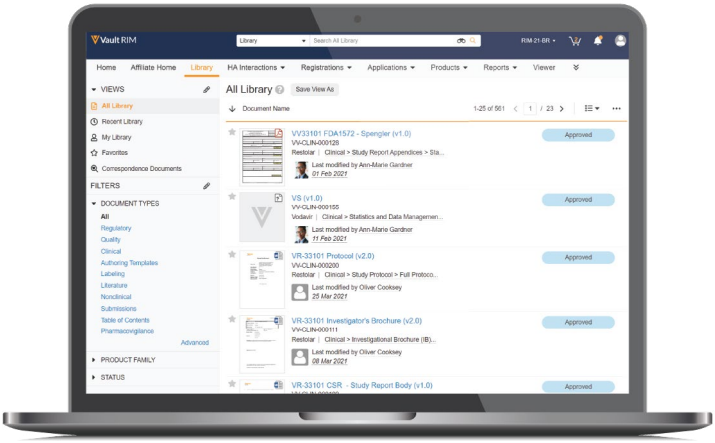
Veeva Vault Submissions

Submission planning, authoring, and assembly



Regulatory information management (RIM) is becoming more complex as new drugs and therapies enter the market and industry standards continue to evolve. Regulatory professionals must figure out how to collect, aggregate, manage, analyze, and act upon a growing volume of data, and legacy technologies like spreadsheets and file shares are no longer sufficient to keep pace.

In addition, many companies that work with affiliates and distributors around the world have difficulty tracking what information they are sending to local health authorities. They often coordinate efforts via email and spend hours duplicating data entry, updating status reports, and responding to questions from headquarters.

Veeva 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.

When used in conjunction with other Vault applications, such as Vault eTMF and Vault QualityDocs, Vault Submissions streamlines interactions between departments. 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.

Benefits

- **Continuous visibility:** Track the progress of regulatory submissions through intuitive reports and dashboards, mitigating risks to timelines.
- **Speed to market:** Automate multiple tasks to speed regulatory submission authoring and assembly.
- **Global alignment:** Maintain greater control over affiliate submissions and health authority interactions.
- **Unified RIM:** Connect end-to-end regulatory processes and improve efficiency as part of the Veeva Vault RIM Platform.

Features

Extensible Content Model

Align content taxonomy (document types, subtypes, properties, etc.) with industry best practices, like eCTD and the DIA EDM Reference Model, and extend to meet specific business needs.

Submission Content Plans

Auto-generate a table of contents for major regulatory submissions, add planned content, and report on submission status in real time. Reuse content plans globally.

Robust Lifecycle Management

Replace manual processes with flexible workflows and lifecycles that guide submission authoring, review, and approval. Authorize individuals to easily change in-process workflows by adding, removing, or emailing participants.

Global Access and Collaboration

Provide authorized users with access through a single, secure cloud location, eliminating the need to bring external users behind the corporate firewall, issue laptops, or provide network IDs.

Health Authority Interactions and Commitments

Retain and classify all correspondence with health authorities. Create commitment records with related tasks and report on progress against outstanding commitments and deliverables.

Collaborative Authoring with Microsoft Office

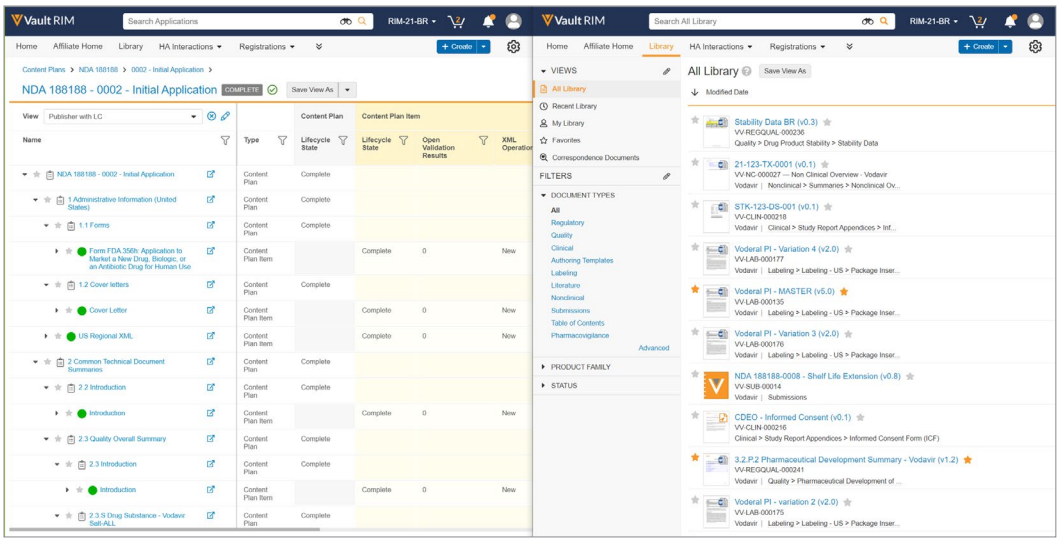
Simultaneously edit documents alongside multiple Vault users while utilizing the full co-authoring capabilities provided by Microsoft Office™. **See a demo**.

Report Level Content Plans

Compile and publish reports, such as clinical and non-clinical study reports, periodic safety reports, and investigator's brochures.Create hyperlinks that are independent of report structure so they can be used earlier in the process during document reviews.

Interactive Dashboards

Drill down through interactive dashboards to narrow in on the exact source of delays. Take action directly from the reports to address hold-ups quickly and stay on track for submission deadlines.



Veeva Vault RIM Platform

Vault Submissions is part of the Veeva Vault RIM Platform, which streamlines global regulatory processes on a single, cloud-based platform. This enables life sciences companies to:

- Ensure teams are developing reliable regulatory content with high data integrity
- Coordinate regulatory efforts across headquarters, affiliates, and partners
- Respond faster to changing regulations
- Increase end-to-end process efficiency from submission planning to publishing