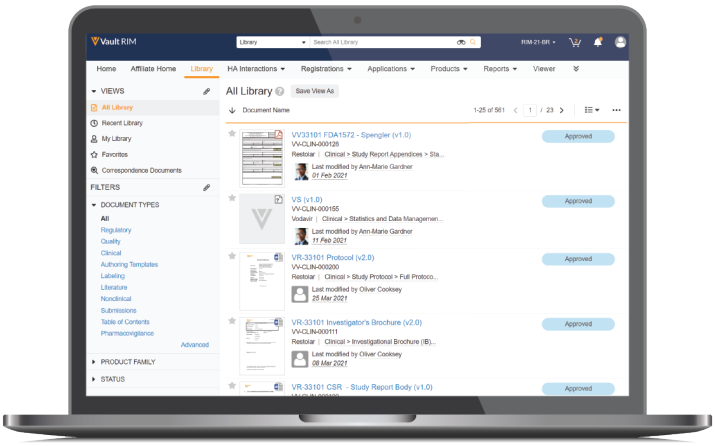
Submissions

Submission planning, authoring, and assembly



Regulatory information management (RIM) is increasingly complex as new medical devices and diagnostics enter the market and industry standards evolve. Regulatory teams must identify ways to collect, aggregate, manage, analyze, and act upon a growing volume of data. Legacy technologies like spreadsheets and file shares are no longer sufficient to keep pace.

Many companies that work with regional affiliates and distributors have difficulty tracking the information sent to local health authorities. Communication with health authorities often takes place via email and status report updates are completed manually.

Veeva Submissions eliminates the need for multiple, siloed tracking systems by providing a single, authoritative source for regulatory submission content in a secure cloud environment. Companies can manage the entire submission lifecycle from planning to publishing with greater access, visibility, and control over their documents and data. Veeva 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 Veeva applications, such as Veeva eTMF and Veeva QualityDocs, Veeva Submissions streamlines interactions between departments. Users can reference source materials from other applications, such as clinical documents, manufacturing details, SOPs, and promotional materials. Each department can leverage content as needed while maintaining a single source of truth across the organization.

Benefits

Streamlined Submission Management

Track the progress of regulatory submissions through intuitive reports and dashboards, mitigating risks to timelines.

Trusted Compliance and Accuracy

Automate multiple tasks to speed regulatory submission authoring and assembly.

Faster Health Authority Approvals

Standardized, automated processes and templates increase efficiency for faster submission timelines.

Unified RIM

Connect end-to-end regulatory processes and improve efficiency as part of Veeva RIM.

Features

Extensible Content Model

Align content taxonomy (document types, subtypes, properties, etc.) with industry standards like the IMDRF Market Authorization Table of Contents and extend to meet specific business needs.

Submission Content Plans

Auto-generate a templated structure for major regulatory submissions, add planned content, and report on submission status in real time. Also, reuse documents from the library across multiple plans and markets.

Global Content Plans

In conjunction with Veeva Registrations, 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. Dispatch content iteratively as it's ready with the ability to compare and review changes before they are committed to a target submission.

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

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

Collaborative Authoring with Microsoft Office

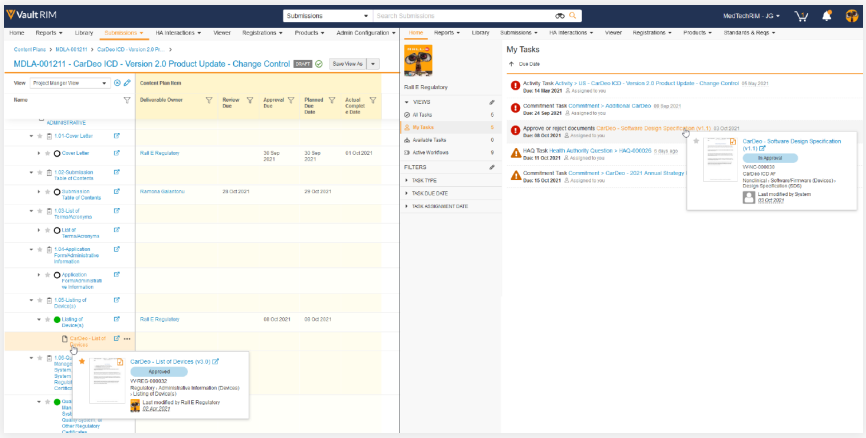
Simultaneously edit documents alongside multiple Vault users while utilizing the full co-authoring capabilities provided by Microsoft Office™. **See a demo**.

Report Level Content Plans

Compile and publish reports, such as clinical and non-clinical study reports. Create hyperlinks that are independent of report structure for use earlier in the process during document reviews.

Interactive Dashboards

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



Veeva RIM

Veeva Submissions is part of Veeva RIM, which streamlines global regulatory processes on a single, cloud-based platform. This enables medtech 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