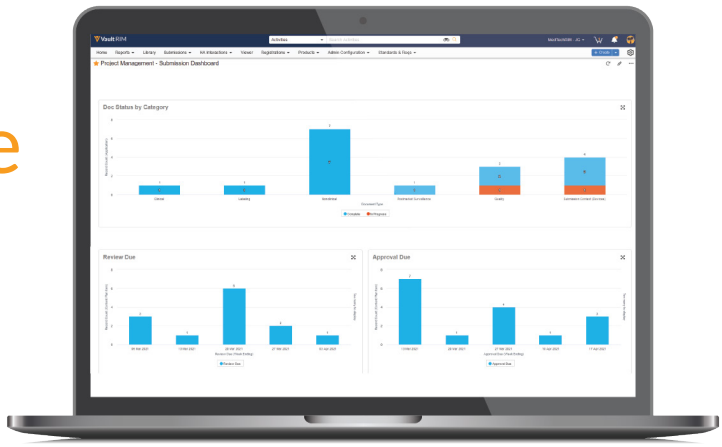
Submissions Archive

Complete history of regulatory submissions



Regulatory teams often use a patchwork of systems to track historical submissions, which create confusion and slow responses to health authorities.

Veeva Submissions Archive stores electronic submissions in a validated cloud environment and links health authority correspondence to related submissions for a complete view into regulatory communications. Affiliates can download submissions or submission components for reuse in local markets and upload submissions already sent to various health authorities.

Veeva Submissions Archive also enables companies to import submissions directly from file shares while preserving the file structure, 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 viewer provides current, sequential, cumulative, and regulatory action views so users can quickly see the full lifecycle of an application.

Benefits

Dynamic access control: Share the right content with the right people based on configured business rules.

Faster responses: Easily locate regulatory dossiers including those sent by regional offices or local affiliates to health authorities.

Global readiness: Allow remote team members to access authorized submissions from anywhere in the world.

Unified RIM: Connect end-to-end regulatory processes and improve efficiency as part of the Vault RIM Platform.

Features

Format-Agnostic Import

Import final submission packages for your records and future reference, whether they are in STED, IMDRF, 510(k), or other formats.

Integrated Viewer

Leverage an integrated, cloud-based viewer, which reduces the number of tools on the regulatory desktop.

PDF Link Navigation

Navigate PDF hyperlinks across documents within a submission and across submissions. There's no need for separate tools, file shares, or downloading files.

Health Authority Interactions

Retain and classify all correspondence with health authorities. View correspondence documents in the context of the application and associated submission. Track and plan health authority questions, commitments, and meetings.

Dynamic Access Control

Use rule-based access control to dynamically calculate permissions that ensure people can see only what they need and nothing else.

Dashboards and Reports

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

Document De-duplication

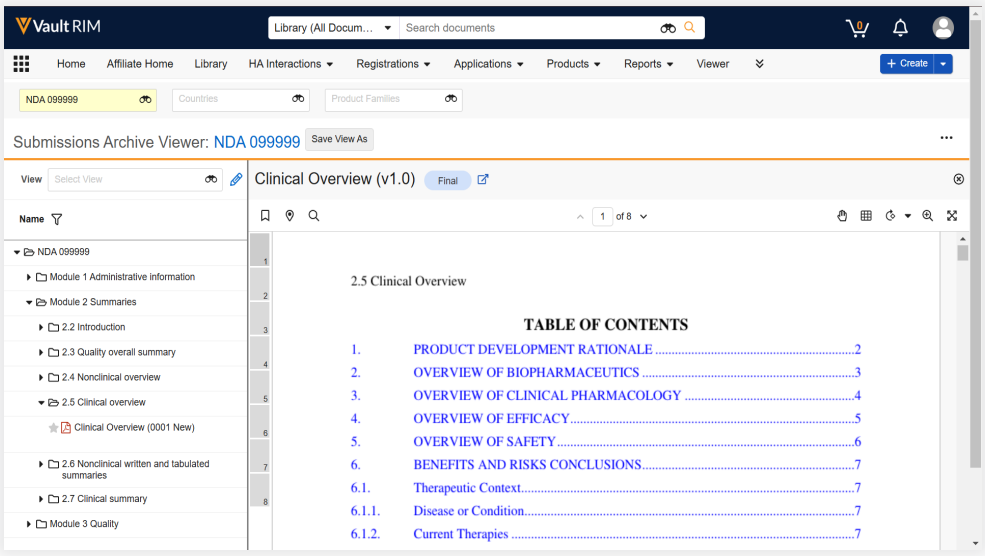
Store documents used in multiple submissions once and only once.

Smarter Navigation Display

Access a document's complete history of lifecycle operations. See where a document is used, including direct links to each submission.

Bulk Submission Export

Quickly export multiple submissions to support product divestitures, collaboration, and outsourced publishing.



Veeva RIM Platform

Veeva Submissions Archive is part of the **Veeva RIM Platform**, 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