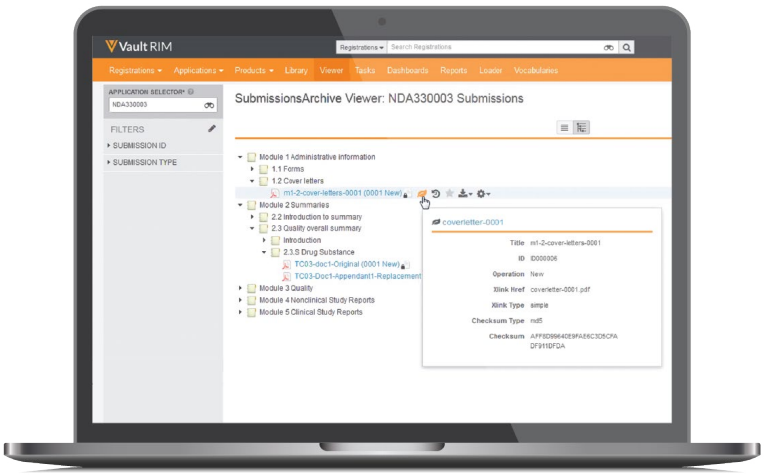
Datasheet

# Veeva Vault 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 Vault Submissions Archive makes it easy to find the right information in a validated cloud environment. Regulatory teams can store eCTD and non-eCTD electronic submissions (NeeS) and link health authority correspondence to related submissions for a complete view of regulatory communications. 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.

## 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 Suite.

# Veeva Vault Submissions Archive

## Features

### eCTD and Non-eCTD Import

Import final submission packages for your records and future reference. Extract and normalize data from the XML to ensure greater accuracy.

### Integrated Viewer

Leverage an integrated, cloud-based viewer for eCTD, NeeS, and legacy submission formats, which reduces the number of tools on the regulatory desktop.

### PDF Link Navigation

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

### Full Lifecycle Viewing

View the complete dossier lifecycle with current, sequential, and regulatory action views. See cumulative changes for each document.

### 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.

### 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.

### De-duplicate Documents

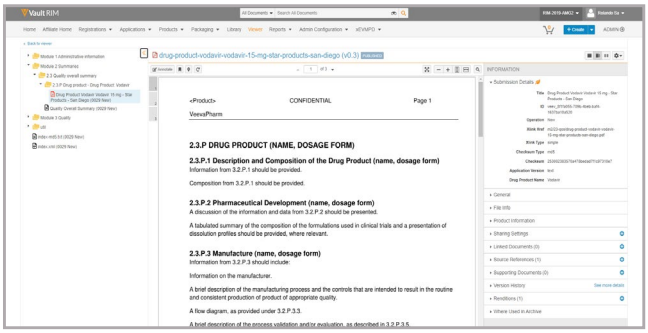
Store documents used in multiple submissions once and only once with the correct leaf details and metadata for each submission.

### 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 Vault RIM Suite

Vault Registrations is part of the Veeva Vault RIM Suite, 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