

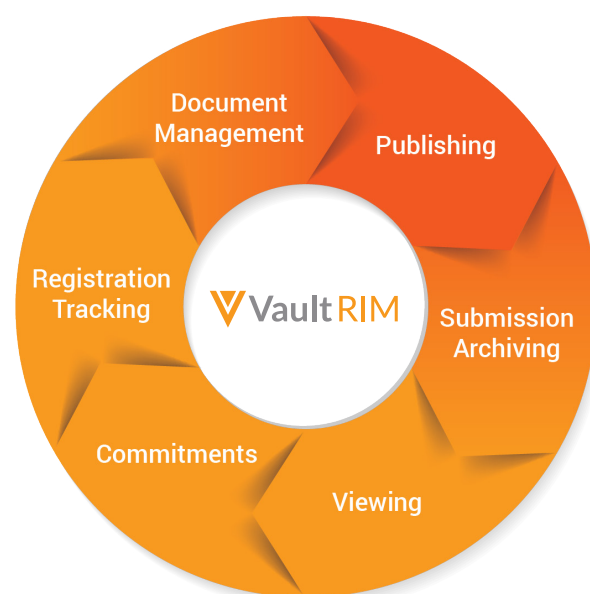
Veeva Vault Submissions Publishing

Behind-the-scenes publishing in a unified RIM solution

Traditional publishing processes are serial in nature and inherently disjointed. Companies often rely on multiple technologies like a document management system, a publishing tool, and one or more spreadsheets for planning and tracking submissions. Each gap between systems introduces inefficiencies and delays.

Veeva Vault Submissions Publishing incorporates capabilities within the Vault RIM Suite to provide a continuous publishing experience that dramatically speeds submission delivery. This eliminates the need for standalone publishing software so teams no longer have to move documents back and forth between systems. Now users can perform publishing tasks like cross-document hyperlinking and validation earlier in the process when issues are easier to fix, and they can avoid multiple rounds of unnecessary internal reviews.

Vault Submissions Publishing is used in conjunction with Vault Submissions and Vault Submissions Archive to streamline the end-to-end publishing process and drive greater automation, transparency, and speed.



Benefits

- **Comprehensive oversight:** Manage end-to-end submission development within a single system.
- **Streamlined processes:** Gain direct access to the correct submission version without manual tracking or document transfers.
- **Shorter timelines:** Regulatory publishing steps are completed earlier—during submission authoring and approvals.
- **Unified RIM:** Connect end-to-end regulatory processes and improve efficiency as part of the Vault RIM Suite.

Features

Assisted Submission Building

Eliminate manual steps with rule-based auto-matching. Leverage documents and metadata from submission content plans.

Submission Independent Hyperlinking

Create hyperlinks that are independent of the submission structure so they can be used earlier in the process during document reviews and reused across multiple submissions.

Background Validation

Automate validation and link testing with a behind-the-scenes service that identifies problems as submissions are being built.

Submission-ready Rendering

Automatically render all documents with the correct PDF standards. Navigate web links, cross references, and tables of contents directly from the viewer.

Real-time Status Reporting

Gain visibility into the complete submission process including submission status and individual document readiness.

Gateway Integration

Transfer submissions through health authority electronic submission gateways, automatically archiving all gateway receipts and responses.

eCTD Support

Stay compliant with eCTD standards across the globe. Non-eCTD support to follow.

The screenshot displays the Veeva Vault RIM Submissions Publishing interface. The main view shows a submission named 'US Submission: 0022' in a 'READY FOR SUBMISSION' state. A progress bar indicates the submission is currently in the 'In Progress' phase. A modal window is open, displaying a warning message: 'Review the information below before transmitting the Submission '0022' for Application: 123456 to the US FDA EDQ.' The modal lists submission details: Application Number: 123456, Submission Number: 0022, Center: CDER, Size: 1 MB, High Validation Errors: 2, Medium Validation Errors: 3, Low Validation Errors: 0, and Other Validation Errors: 0. Below the modal, the 'Open Validation Results' table is visible, showing a list of errors with columns for Name, Severity, Occurrences, Description, Problem, and Corrective Action.

Name	Severity	Occurrences	Description	Problem	Corrective Action
7	High / Fail / Error	1	1 Filable form not included	You have submitted without inclu...	Resubmit with the appro...
5045	Medium / Warning	1	1 PDF opening settings not optimal	You have submitted a PDF that d...	Ensure that PDF Opening
5005	Medium / Warning	1	1 Non standard font (not embedded)	You have used a non-standard fo...	Resubmit a corrected leaf
5005	Medium / Warning	1	1 Non standard font (not embedded)	You have used a non-standard fo...	Resubmit a corrected leaf
1789	High / Fail / Error	1	1 A file has been submitted in a stud...	All files in a study section must b...	In a new submission inclu...

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