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 Platform 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.



Business Benefits

Comprehensive oversight.

Manage end-to-end submission development within a single system.

Shorter timelines.

Regulatory publishing steps are completed earlier—during submission authoring and approvals.

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Streamlined processes.

Gain direct access to the correct submission version without manual tracking or document transfers.

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Unified RIM.

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

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-thescenes 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

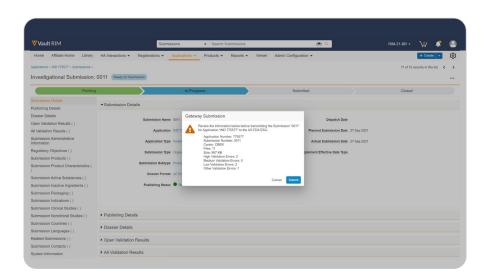
Transfer submissions through health authority electronic submission gateways, automatically archiving all gateway receipts and responses.

eCTD Support

Stay compliant with eCTD and non-eCTD standards across the globe.

Granular Document Merging

Ability to merge submission-ready documents across an entire content plan or part of the content plan to meet agency requirements.



Veeva Vault RIM Platform

Vault Submissions Publishing 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

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