

PRODUCT SHEET

# Vault RIM

Vault RIM unifies regulatory systems and processes on a single cloud platform to enable end-to-end submission and registration management.

RIM applications share a common data model, which allows for regulatory business functions to run in one Vault.

**Vault Registrations** plans, tracks, and reports on global health authority product registrations and associated changes.

**Vault Submissions** is a content management application used to plan, author, review, and approve regulatory submissions.

**Vault Submissions Publishing** produces compliant published submissions ready to send to global health authorities.

**Vault Submissions Archive** provides storage, navigation, and search of submitted regulatory applications and related correspondence and questions.

PRODUCT	ANNOUNCED	STATUS	CUSTOMERS
<b>Vault Registrations</b>	2015	Mature	100+
<b>Vault Submissions</b>	2013	Very Mature	100+
<b>Vault Submissions Publishing</b>	2017	Mature	51–100
<b>Vault Submissions Archive</b>	2015	Mature	100+

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# Vault Registrations

Registrations allows sponsors to plan, track, and report on global product registrations along with health authority correspondence and commitments.

Events provide the ability to manage product changes, from the initial assessment of the proposed change through submission creation, health authority interactions, and final registration update. Label changes can be tracked and managed at both the global and local level. Registrations also produces compliant product data output (e.g., xEVMPD and IDMP) for EU regulations.

Dashboards and reports allow personnel to track the progression of change events and provide an understanding of product registration locale.

<b>Announced</b>	2015
<b>Status</b>	Mature
<b>Customer type</b>	Enterprise Pharma, Biotech, CDMO, MedTech, Consumer
<b>Customers</b>	100+
<b>Platform</b>	Veeva Vault
<b>Integrations</b>	Lives with Submissions, Submissions Publishing, Submissions Archive Connected with QMS

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# Vault Submissions

Submissions is the leading content management application used to plan, author, review, and approve regulatory documents. It provides full enterprise content management capabilities for creation, version control, approval, and real-time co-authoring for all submission-related documents. With content planning capabilities, users can build a submission outline and automatically match documents to the outline.

Clinical and non-clinical reports can be built and published using Report Level Content Plans. Dashboards and reports allow submission managers to track the status of each document in real time.

<b>Announced</b>	2013
<b>Status</b>	Very Mature
<b>Customer type</b>	Enterprise Pharma, Biotech, CRO, CDMO, MedTech, Consumer
<b>Customers</b>	100+
<b>Platform</b>	Veeva Vault
<b>Integrations</b>	Lives with Registrations, Submissions Publishing, Submissions Archive Connected with eTMF, PromoMats

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# Vault Submissions Publishing

Submissions Publishing generates electronic submissions for global health authorities. Veeva releases new templates and validation criteria to keep up with evolving regulations. Submissions Publishing leverages content plans created earlier in the lifecycle to start the publishing process as soon as individual documents are finalized.

Users can create internal and external hyperlinks to connect references in the text. They publish submissions directly to health authorities from Vault, in markets where allowed.

Dashboards and reports allow publishers to track each submission component as it progresses from authoring to completion.

<b>Announced</b>	2017
<b>Status</b>	Mature
<b>Customer type</b>	Enterprise Pharma, Biotech, CDMO, MedTech, Consumer
<b>Customers</b>	51–100
<b>Platform</b>	Veeva Vault
<b>Integrations</b>	Lives with Registrations, Submissions, Submissions Archive Requires Submissions, Submissions Archive

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# Vault Submissions Archive

Submissions Archive is a global, secure repository of submission published output. It functions as the authoritative source of applications submitted to health authorities.

Submissions Archive includes a viewer that supports all electronic and paper formats, with PDF link navigation provided for electronic formats. Users can view submissions and health authority correspondence alongside all previously submitted applications.

The embedded document viewer provides visibility into each document in the structure.

The Active Dossier feature displays the submission components that are currently active for any product / market combination.

<b>Announced</b>	2015
<b>Status</b>	Mature
<b>Customer type</b>	Enterprise Pharma, Biotech, CRO, CDMO, MedTech, Consumer
<b>Customers</b>	100+
<b>Platform</b>	Veeva Vault
<b>Integrations</b>	Lives with Registrations, Submissions, Submissions Publishing