Veeva RIM

End-to-end RIM on a unified platform

For most medtech companies, coordinating regulatory information management (RIM) activities across global markets is incredibly complex. Companies struggle with poor data quality, inefficient collaboration, and limited visibility due to disjointed processes and siloed systems. Streamlining these operations is critical for accelerating product time to market while remaining compliant.

Veeva RIM provides an authoritative source for regulatory documents and information globally. Content and data converge in a single cloud platform for unified registration tracking, health authority interactions, submission document management, dossier publishing, and regulatory submission archiving.

A unified solution simplifies data entry and document upload, reducing manual effort while increasing visibility and collaboration, ensuring accurate, timely, and accessible information. Veeva RIM also improves end-to-end regulatory process efficiency, enabling faster responses to product changes, compliance concerns, and health authority requests.

Benefits

Accelerate Speed to Market

Faster submission assembly and publishing through increased visibility and collaboration.

Real-Time Data-Driven Decisions

Enable data-driven decisions across all steps of the submission lifecycle.

Automated Compliance Updates

Adapt seamlessly to evolving global regulatory requirements with automated updates.

Always Current

Receive new functionality three times a year to keep you current with technological advances and emerging regulatory requirements.

Platform Features

Health Authority Interactions

Retain and classify all correspondence with health authorities. Extract and track questions from health authorities as well as plan and author responses to questions. Also, track commitments to health authorities and related meetings.

Dashboards and Reports

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

Global Content Plans

Centrally assemble global or core documents related to a multi-market change for streamlined content reuse across local submissions, including those with varying submission structures.

Applications

Veeva Registrations

Veeva Registrations provides a single, comprehensive solution to manage product registration data worldwide, license changes, and renewals. Companies can manage registration information such as approved product variants, packaging configurations, and systems configurations across all global markets. Medical device product registration data is modeled to conform with US and EU UDI guidelines. As a shared resource for headquarters and affiliates, Veeva Registrations helps globally standardize key processes and improve data quality.

Veeva Submissions

Veeva Submissions manages authoring, planning, collection, and approval of documents for submission to regulatory authorities. Veeva Submissions supports industry-standard content formats such as the IMDRF Table of Contents as well as market-specific formats like eSTAR to ensure that the content taxonomy aligns with industry norms and facilitates collaboration with external parties. Submission content plans show expected documents and track submission completeness in real time without manual updates. Templates and placeholders assist with the creation and collection of required materials, while Vault's reporting and approval workflows ensure necessary documents are included and complete. With Registrations, core documents for multi-market changes can be assembled at the global level and bulk dispatched to various target submission structures.

Veeva Submissions Publishing

Veeva Submissions Publishing seamlessly incorporates continuous publishing within Veeva RIM to dramatically speed submission delivery. Now regulatory teams can perform cross-document hyperlinking and validation earlier in the process when issues are easier to fix. Veeva Submissions Publishing is used in conjunction with Veeva Submissions and Veeva Submissions Archive to streamline the end-to-end publishing process and drive greater automation, transparency, and speed.

Veeva Submissions Archive

Veeva Submissions Archive stores a complete history of regulatory submissions in a secure cloud environment. A high-performance cloud architecture makes access to published submissions fast and easy. Affiliates can download submissions for reuse in local markets. Veeva Submissions Archive imports submissions directly from file shares while preserving the folder structure and relative document hyperlinks. Users can navigate documents exactly as they were submitted to regulatory agencies and directly from the repository without downloading files.