

Innovative Biotech Leader Builds a Connected RIM Experience

Phased Approach Optimizes Veeva Vault RIM Implementation

After its first drug approval, this innovative biotech organization quickly evolved from a single-product, single-market company into a leader with multiple commercial products and an expanding global footprint. Yet they still managed regulatory processes with a mix of spreadsheets, emails, SharePoint, and file shares.

From Disconnected Tools to a Single Platform

The biotech company selected Veeva Vault RIM to modernize their regulatory technology on a global scale. They embarked on a phased, 18-month rollout to completely transform how they manage regulatory submissions, health authority interactions, archiving, viewing, and registration tracking. By centralizing regulatory information and providing end-to-end process visibility, Vault RIM is helping the global regulatory team keep pace with the company's rapid growth trajectory.

Regulatory Activity	Before	With Vault RIM
Submission Planning	Manual tracking in spreadsheets and SharePoint sites	Auto-generated submission plans with connected documents and real-time status
Submission Document Authoring	Ad hoc process with emails, SharePoint, and review-and-approval software	Simplified process with standard workflows, templates, and e-signatures
Submission Document Storage	Documents spread across various SharePoint sites and file drives	Consolidated submissions archive with powerful search capabilities
Health Authority Interactions	Manual tracking in spreadsheets and via individual tracking	All interactions and correspondence tracked and accessible in one place

Successful User Adoption

During their Vault RIM implementation, the biotech organization prioritized efforts to deliver a positive experience for their regulatory user community. The company leveraged Veeva's train-the-trainer materials to create a variety of learning resources targeted at different roles and functions. They also designed a robust communications program, which prepared people for change by sharing important developments in targeted emails. Lastly, a carefully designed migration strategy ensured that users had access to critical regulatory data and documents on day one.

Moving forward, the biotech leader will bring together regulatory, quality, and clinical information with Veeva's Vault to Vault connections to enhance visibility across the organization.