moderna™

Moderna Improves Health Authority Query Management with Veeva Vault RIM

HIGHLIGHTS

Deployed a new HA query managment process in < 5 weeks

Enhanced visibility into past responses and current queries

Streamlined responses to keep pace with 15x increase in submissions

Like many small teams, Moderna's regulatory organization relied on spreadsheets to track health authority (HA) questions and responses. When the pandemic hit, the number and urgency of HA queries increased dramatically as Moderna moved swiftly to release a COVID-19 vaccine. To keep pace, their regulatory team needed a more proactive, efficient way to respond to HA requests.

Fortunately, a solution was close at hand. In less than five weeks, Moderna was running a faster, more scalable HA query management process with Veeva Vault RIM.

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Company size: 2,700+
Headquarters: Cambridge, MA

VEEVA SOLUTIONS

Veeva Vault Registrations
Veeva Vault Submissions
Veeva Vault Submissions Archive

Increasing Efficiency of Responses

Despite receiving similar questions from multiple health authorities, Moderna's subject matter experts often spent valuable time addressing them separately. They managed questions in a spreadsheet that was uncoupled from the correspondence documentation, which made it difficult to navigate especially with so many global users. If Moderna's experts couldn't easily find a related answer in the tracking spreadsheet, they authored a new response—raising the risk of delays and inconsistent replies.

Now with Vault RIM, subject matter experts can easily determine whether a question has been asked before. Unified data and documents enable them to quickly filter more than 1,600 queries and answers, along with the

full text of each correspondence file, to find and reuse relevant responses. This increases response efficiency and improves the consistency of information sent to global health authorities.

Moderna can also use the HA question object within Vault RIM to assign and track response progress, allowing internal and external experts to collaborate on responses and ensure their completeness and accuracy.

Managing More HA Queries

With Vault RIM, Moderna was able to scale up to handle an ever-growing volume of HA queries. Regulatory can now drive faster responses and quickly address hold-ups with real-time visibility into HA queries by country, product, priority, and assignee. Queries can also be assigned to teams of subject matter experts with specific deadlines so they know which of their assigned questions to focus on first.

Since the onset of the pandemic, Moderna's regulatory submissions have grown from 127 to 2,000+ a year—a massive 15x increase. But with a streamlined HA query management process, they'll be able to keep approvals on track as they develop an exciting pipeline and continue to manage their global COVID-19 vaccine products.

Learn more at veeva.com | **925-452-6500** | **veeva.com/contact**