ATARA BIO

Atara Establishes a Foundation for Growth with Veeva Vault RIM

Elevating the role of regulatory technology to support change

Since 2016, Atara Biotherapeutics has worked with Veeva to centralize regulatory data and documents, align cross-functional teams, and automate manual processes. As the biotech company continues to grow, Veeva Vault RIM is evolving with them to help keep pace in a rapidly changing environment.

> **ATARA BIO – AT A GLANCE**
> - **Corporate Headquarters: San Francisco, CA**
> - **Employees: 400+**
> - **Primary Therapeutic Area: T-cell Immunotherapy**

Accelerating the Delivery of Business Value

In early 2020, Atara kicked off an initiative to better prepare its regulatory organization for the future. The company was underutilizing Vault RIM, so it launched an optimization program to maximize the solution's existing value while also adding new capabilities to prepare for anticipated growth. Atara focused its efforts on improving Vault Submissions, adopting Vault Registrations for registration tracking, and Vault Submissions Publishing to support in-house publishing of upcoming marketing applications.

In parallel, Atara overhauled its system implementation practices to streamline validation efforts and bring new functionality to users. The company adopted an agile, risk-based approach to validating new functionality that allowed for more frequent, incremental upgrades and improved user adoption. These methodology updates continue to accelerate the deployment of Atara's configuration changes along with innovations in Vault RIM's regular release cycles.

Faster Submissions with Continuous Publishing

Atara activated Veeva Vault Submissions Publishing to streamline the European MAA submission for its inaugural commercial product, marking it as the first approved allogeneic T-cell cancer therapy.. Previously, the company had outsourced its submission publishing projects, relying on disjointed folders and binders to manage information and document exchanges with contract partners.

Matt Neal, head of regulatory affairs and quality, sought to bring these efforts in-house, believing that a continuous publishing approach would eliminate the time constraints from traditional submissions publishing tools and approaches. The primary objectives included facilitating earlier review, handoffs, and rework management in the publishing process, while also distributing project management responsibilities across teams.

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> *A RIM system starts to become a strategic asset for organizations that do it right.*
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> — Matt Neal, Senior Director Regulatory Affairs Operations, Atara Biotherapeutics

Veeva's platform streamlined Atara's submissions publishing and removed bottlenecks by centralizing access to required documents and information. Expert authors can now collaborate, link, and create content independently and in parallel, accelerating review and validation times and reducing time constraints. Authors and publishers can also work together on an overall content plan that addresses key project management issues like author and reviewer workloads. Gaining cross-functional transparency eliminates risks from one person managing all the tasks across multiple teams.

The platform has "unleashed power that users didn't know they had," says Neal, by leveraging Vault RIM's real-time access to documents and data throughout the product life cycle. Improved data access can reduce the risk of receiving "refusal to file" responses from regulators by exposing documentation gaps earlier in the cycle. For Atara, the new platform has elevated the submissions publishing professional's role to that of an advisor, Neal adds. "Not on the science or clinical side, perhaps, but on how the submission should look when it reaches regulatory agency reviewers."

Capabilities Continue to Evolve and Expand

The unified Vault RIM solution is fast becoming a strategic asset to Atara, and will continue to evolve as the company prepares for commercialization. They now have access to information that's connected and readily available in an authoritative system, which supports faster, more effective decisions. As a result, Atara staff are starting to see improvements in operational processes and in the quality of their work products.

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