Amgen Transforms Regulatory Operations with Veeva Vault RIM

Global RIM solution streamlines processes and information access

In 2016, Amgen initiated a transformational, multi-year project to modernize its regulatory systems. With an expanding product portfolio and global presence, Amgen needed to adopt more efficient IT tools and processes to streamline submission planning, review, and tracking.

AMGEN – AT A GLANCE

- **Corporate Headquarters: Thousand Oaks, CA**
- **Employees: 23,000+**
- **Primary Therapeutic Areas: Heart disease, oncology, bone health, nephrology, inflammation**

Data and Documents in One Global Platform

Amgen selected Veeva Vault RIM to bring together regulatory data and documents in a single, authoritative source of truth. The company phased multiple, global go-lives over the course of two years and incrementally added capabilities, users, data, and documents to their RIM solution.

The Vault RIM Suite rollout concluded in late 2020 with Vault Submissions Archive. Users across the company now plan, execute, and track submissions and health authority interactions on a common platform with end-to-end process visibility into all regulatory activities. The mission-critical RIM solution houses all regulatory documents and integrates with a multitude of business systems.

Continuous RIM Improvements

Change management and end-user involvement were critical to the program's success. The RIM project team partnered with 200 subject matter experts and 160 change champions to ensure organizational readiness. As a result, users shared positive feedback on system workflows, usability, and the speed of information access, which encourage system adoption.

The transformation journey at Amgen is just beginning. A governance team is in place to manage the ongoing evaluation of the technology and to oversee enhancements to the end- user experience, including new process improvements and system integrations. In addition, Amgen has started onboarding development partners to Vault RIM to coordinate regulatory activities around the globe.

> *Thinking about this as a technology project is not correct. You really have to help people transform the way they work.*
>
> *– **Dominique Lagrave,** Head Global Regulatory Operations, Amgen*