moderna

How Moderna is Automating Change Control and Variation Management

Vault Quality to RIM Connection streamlines previously time-consuming and manual processes across regulatory and quality

Moderna Therapeutics pioneered mRNA technology to develop vaccines and therapies that scale quickly, reduce risk, and adapt to different targets. So far, its efforts have paid off, as shown by the record-setting development timelines seen with Spikevax, its mRNA vaccine for COVID-19.[1]

While Moderna's work on Spikevax is critical, it is only one of the company's global initiatives. Moderna is investing in overall R&D agility and nurturing its growing pipeline, which currently consists of 40 developmental vaccines and therapies for rare and infectious diseases and oncology. Clear and consistent guidance from senior management and a mantra of "scale and collaborate" have helped them prioritize the projects that will bring the most value, says Juhi Saxena, Moderna's associate director of regulatory and clinical platforms, who joined the company during the COVID-19 pandemic.

To facilitate these ambitious plans, Saxena and her team are automating manual processes and integrating business groups to improve collaboration. "We're a platform company and we believe in digitization and integration," she comments.

Automating change control

To increase overall agility, Saxena's team decided to streamline change control management, a costly and time-consuming process that involves regulatory and quality departments. Most companies still use manual, disconnected, and redundant change control processes that put companies at risk of noncompliance and can delay the launch of new therapies.

For example, impact assessments, which measure the effect of changes on various product characteristics in different locations, are cumbersome when approached with traditional tools and methods. At most companies, the assessment is first done in RIM but must be replicated in QMS. Tracking data and communications across teams is difficult because data is typically stored on different spreadsheets in different countries, so there is very little transparency and a lot of manual effort.

Moderna previously deployed Vault Registrations and Vault QMS, and because both applications use a common data framework, Saxena's team had a unique opportunity to leverage the Vault Quality to RIM Connection. This made change control management more efficient by eliminating redundant manual processes and making data easier to find and share. Both regulatory and quality can now initiate processes and transfer data to each other in real time, empowering quality teams to make decisions sooner and based on the right information.

---

[1] Bancel,S., remarks made in "COVID-19 Vaccine Development and Its Enduring Impact on Life Sciences Innovation, Speed, Clinical Trial Advancement, and Collaboration," Galien Foundation Forum, October 29, 2020, www.youtube.com/watch?v=JVvX2PUFIAQ&ab_channel=TheGalienFoundation

After connecting Veeva Vault QMS and RIM, the data and information required for change control doesn't have to be requested or sit in someone's inbox for two days. This has significantly reduced the time required to perform regional impact assessments and send that information on to supply chain and quality departments.

— Juhi Saxena, Associate Director of Regulatory and Clinical Platforms, Moderna Therapeutics

On a fundamental level, the connection also gives both quality and regulatory departments a much better understanding of each other's strategies, constraints, and operations. Previously, workflows involving the two teams required several rounds of back-and-forth communication. Now, the process is well defined and consistent, and users must follow specific steps within a certain amount of time, Saxena explains.

The benefits of connection

By deploying the Vault Quality to RIM Connection, the regulatory team automatically sends country assessments to the quality department. "Now, the data points and relevant information don't have to be requested, or sit in someone's inbox for two days," Saxena says. This has significantly reduced the time required to assess regional impacts of manufacturing or other changes and send that information on to the supply chain and quality departments so that they can perform lot distribution.

Having relevant quality and regulatory data and documentation in one place also reduced the risk of noncompliance, Saxena explains. "We have a proper audit trail in place, and if we need to, we can always go back and see which action was performed when and by whom. Beyond its compliance benefits, the connection facilitates the development of better processes for strategy and CMC within the regulatory department, and for supply and distribution within the quality department," she adds.

Users can also access historical data to see what decisions were made so they can build on that information when they encounter a change for the same drug product or one from the same product family.

In the future, Saxena plans to explore additional benefits that the connection could bring. For example, having access to historical data could lend itself to developing predictive models that would improve future regulatory and quality decisions based on what has worked well in the past. For now, the Vault Quality to RIM Connection helps reduce manual and redundant tasks, allowing Moderna's teams to focus on patients and adapt to changing work processes as the company and its pipeline of therapies and vaccines continue to grow[2].

[2] Byrne, J." Moderna to expand commercial network across six additional countries in Europe," Biopharma-Reporter, February 17, 2022.