



Arcus Biosciences Improves Inspection Readiness with Veeva Vault RIM

Harmonized RIM System Brings Efficiency and Control

Founded in 2015, Arcus Biosciences is rapidly evolving into a fully integrated biopharmaceutical company focused on cancer therapies. To ready the company for growth and regulatory inspections, Arcus transitioned from an uncontrolled environment of emails and SharePoint sites to a validated RIM system. The move addressed multiple deficiencies, including a lack of version control, distribution control, audit trails, and standard business processes.

Three-Month Implementation Managed Remotely

Arcus selected Veeva as its technology partner because the unified Vault Platform met its needs across regulatory, quality, clinical, and medical affairs.

Within regulatory, Arcus deployed Vault Submissions and Vault Submissions Archive to bring together documents and data. The implementation involved a lot of upfront preparation and user participation since the company was essentially starting from scratch. The project team led six critical workstreams to ensure a successful rollout: IT infrastructure, business process, system configuration, training, data migration, and validation. The project took just three months from kick-off to go-live, an aggressive timeline that was made even more challenging by COVID-19.

ARCUS BIOSCIENCES – AT A GLANCE

- Corporate Headquarters: Hayward, CA
- Employees: 125+
- Primary Therapeutic Area: Immuno-Oncology

Standard Submissions Process in a Validated System

Arcus launched Vault RIM in June 2020 with a robust training program that eased the transition for more than 60 users. The company now has a single, secure authoritative source for submissions content. Regulatory staff work more efficiently and follow standard, auditable processes from submission planning through approval.

Arcus's RIM journey is ongoing. The company has shifted its focus to post-launch activities, including training for infrequent users and new hires. The company also hosts a monthly user forum to address questions, resolve issues, and solicit ideas for system enhancements. Arcus will continue to evolve its RIM solution by acting on this feedback.

/// *The implementation is the beginning of the conversation with your customers, it's not the end.* ///

– **Lisa Owens**, Senior Director of Regulatory Operations at Arcus Biosciences