

Developing a Veeva QMS Adoption and Governance Roadmap for a Commercial-Stage Biotechnology Company

INDUSTRY



Biotechnology

PRODUCTS AND SERVICES



Novel therapies and
treatments for B-cell diseases

BUSINESS TRANSFORMATION STORY & BUSINESS CHALLENGE

The client is a fully integrated, commercial-stage biotechnology company focused on advancing novel treatments for B-cell diseases. As the organization scaled, Veeva QMS became a critical platform for managing quality processes, documentation, training, and compliance activities across the organization.

Although users valued the platform and the Quality team's support, onboarding and usability challenges affected confidence and efficiency. Documentation-heavy training lacked practical, role-specific guidance, and users struggled to connect quality processes with Veeva workflows and locate information within increasingly complex processes. Additionally, governance and enhancement prioritization remained largely concentrated within Quality, limiting broader business participation and reducing opportunities to improve the overall user experience.

To address these challenges, the client partnered with Clarkston Consulting to conduct a comprehensive Veeva QMS training and process assessment, focusing on user adoption, governance structures, and system configuration. The objective was to evaluate current-state processes to identify opportunities for improvement and develop a practical roadmap to strengthen business ownership, improve user confidence, simplify processes, and maximize the value of the organization's Veeva QMS investment.

PRIMARY OBJECTIVES

- Assess current Veeva QMS training materials, onboarding processes, and supporting documentation, as well as system configuration
- Evaluate implemented Veeva QMS workflows, governance structures, role alignment, and process ownership
- Engage cross-functional stakeholders to understand current challenges and barriers to adoption
- Identify opportunities to improve user proficiency, efficiency, and confidence when executing quality processes within Veeva QMS
- Assess organizational readiness, change management practices, and business ownership of the platform
- Develop a prioritized roadmap of actionable recommendations to improve governance, process alignment, user adoption, and system enablement



RESOLUTION

- Conducted a five-week assessment of Veeva QMS processes, training materials, governance practices, and user adoption across the organization
- Interviewed 17 cross-functional stakeholders and surveyed an additional 47 users to gather quantitative and qualitative feedback on training effectiveness, process understanding, usability, and adoption challenges
- Reviewed existing training documentation, job aids, SOPs, work instructions, organizational structures, support requests, and enhancement backlogs
- Assessed key Veeva QMS processes and workflows, including Change Control, Deviations, Continuous Improvement, Audits, and Complaints
- Evaluated role structures, process ownership, governance models, and enhancement management practices to identify opportunities for stronger business engagement
- Analyzed user feedback and assessment findings to identify themes across governance, process complexity, user adoption, and system usability
- Developed a comprehensive recommendations roadmap focused on governance, process optimization, adoption enablement, training modernization, and system optimization
- Delivered an executive-level assessment readout, future-state governance model, business champion framework, training strategy, adoption plan, and continuous improvement roadmap

KEY BENEFITS

- Established a clear understanding of current-state strengths, adoption barriers, and process challenges impacting Veeva QMS effectiveness
- Delivered a prioritized roadmap to strengthen governance, increase business ownership, and improve cross-functional participation in platform decisions
- Defined a scalable user adoption strategy focused on role-based onboarding, practical learning experiences, and business champion enablement

KEY BENEFITS

- Identified opportunities to simplify workflows, improve alignment between business processes and system execution, and reduce user friction
- Provided a structured framework for continuous improvement, including process ownership, adoption metrics, enhancement prioritization, and governance practices
- Positioned the client to maximize its Veeva QMS investment through improved user confidence, stronger business engagement, and ongoing optimization

KPIs

- 5-week assessment of Veeva QMS processes, governance, and user adoption
- Interviewed 17 Veeva QMS stakeholders and surveyed 47 Veeva QMS users to inform recommendations
- Provided recommendations based on review of Veeva QMS-related artifacts (*org charts, policies, manuals, support requests, job aids, SOPs, work instructions, and request backlog*)
- Reviewed implemented Veeva processes and workflows and applicable configuration across change control, deviations, continuous improvement, audits, compliance, and all child objects