

Streamlining Audit Management and Planning for a Biotech Company

Clarkston partnered with a leading RNAi therapeutics company to provide the Global Quality Assurance Team with dynamic, streamlined audit dashboarding capabilities in Smartsheet to support audit planning, resource allocation, and ongoing audit activity tracking. The implementation reduced the 8+ hours a week that were being dedicated to manually aggregating data from Veeva and transposing 100+ audit pipelines into a static, corruptible Excel sheet.

To increase visibility to audits and Quality key performance indicators (KPIs), Clarkston provided the client with resource management capabilities to fuel audit schedules and plans in Smartsheet. Additionally, role and regional-based views now proactively encourage auditor input in the planning phase, and trackable workflows will dedicate attention to current audits to increase the percentage of on-time closures.

Life Sciences Case Study

PROJECT OVERVIEW



INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



Biotech,
RNAi therapeutics

PRIMARY OBJECTIVES:

- Document organizational and functional requirements related to audit management processes
- Automate previously manual data pulls and comparisons from Veeva
- Ease the planning and resource allocation process for GMP/GDP audits
- Manage resources and alignment of auditor(s) to specific audit records
- Provide visibility into audit activities to facilitate on-time audit closure

RESOLUTION:

- Translated 100+ audit records from Veeva to Smartsheet
- Built dynamic, high-level dashboards to provide insights to recent vendors audits, questionnaires, and other activities
- Streamlined resource planning functionality to provide scheduling and bandwidth insights during the auditor allocation process
- Implemented custom schedule views to outline auditors' upcoming audits
- Customized automated workflows to track audit KPIs from planning and initiation to audit closures

KEY BENEFITS:

- Streamlined audit activities through the development of structured templates for the various audit workflows
- Created dedicated, live master data sheets that can be simultaneously leveraged by the Global QA team, tagging all user input to the unique identifier and audit numbers
- Increased visibility across the organization to upcoming and closed vendor audits, on-time closure metrics, and key observations trends

KPIs

- **Eliminated 8+ hours a week spent on the manual aggregation of Veeva data**
- **Created role-specific workflows and dashboard views for all in-scope QA activities**
- **Created a separate trackable report to call out any data updates in Veeva, ensuring data is accurate**
- **Provided managers with team-specific views to be leveraged when discussing prioritization while holding weekly meetings**

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