

Establishing a Data Integrity Governance Program for a Biotech Company

Through rapid growth and commercialization, the client, a leading biotech company, identified the need for broad modernization of their policy, data integrity, governance, and risk management practices, revisiting specific areas for evaluation. Efforts were further accelerated following a regulatory inspection.

Clarkston Consulting was identified as the trusted partner to execute a strategic initiative to meet the evolving compliance requirements.

Over the course of the engagement, Clarkston supported the client by maturing and advancing their data integrity and data governance program. The Clarkston team delivered significant improvements in data integrity governance and operational improvements including major updates to corporate data integrity policy with strategies to implement this new understanding of data integrity. As a result, these efforts allowed the client to focus on manufacturing their life-saving treatments knowing that operations were adhering to regulatory requirements.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



The client manufactures novel immuno- and gene therapies targeting a wide variety of illnesses including cancer, cardiovascular disease, and autoimmune disorders which are marketed globally.

PRIMARY OBJECTIVES:

- Author required policies, SOPs, or guidelines to introduce data integrity operating principles
- Define a high-level data integrity strategy that supports corporate vision
- Develop a project charter and project plan for remediation workstreams to address data integrity improvements
- Prepare area owners for health authority inspection of data integrity related topics

RESOLUTION:

- Authored corporate policy on data integrity and data governance and developed a control strategy
- Created a remediation program to resolve new and/or outstanding data integrity deficiencies in procedures, computerized systems, and risk management practices
- Partnered with senior leadership to define a program management strategy
- Developed, trained, and supported personnel on a novel risk assessment technique for determining audit trail review frequency
- Partnered with cross-functional teams to author procedures that enable process mapping and risk identification
- Evaluated legacy corrective and preventative actions and provided recommendations
- Generated a recurring report examining the effectiveness of major actions

KEY BENEFITS:

- Rapid closure of several critical corrective and preventative actions
- Knowledge transfer to personnel from Clarkston's data integrity experts
- Improved data integrity compliance profile
- Ensured satisfactory follow-up inspections



KPIs

- Assessed 2,700 documents for adherence to standards
- Prepared 25 storyboards over 80 working sessions
- Coached over 60 stakeholders for audit preparation
- Reviewed and categorized over 150 corrective and preventative actions

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