

Developing a GMP Data Integrity Training Program for a Biotech Company

The client, a leading biotech company, recognized the need for a custom training program centered on rapidly advancing knowledge of data integrity and improving the overall data integrity culture by establishing a common awareness of key concepts.

Clarkston Consulting was selected as the trusted partner to design and develop courses ranging from fundamental GDP / CGMP and data integrity topics, to educating on many elements of data governance and industry best practices related to data integrity controls.

During the engagement, Clarkston supported the client by developing a training plan as well as ways to measure the effectiveness of the training following deployment. The Clarkston team delivered 20+ courses designed for either computer-based or instructor-led delivery. These efforts, driven by specialized expertise, led to the development of a robust training program that prepared the workforce with the knowledge to maintain compliance with regulatory standards.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES:



Global manufacturing of immuno- and gene therapies

PRIMARY OBJECTIVES:

- Support the development of a data integrity training plan
- Develop all courses identified in the training plan
- Partner with area subject matter experts to tailor course content and objectives
- Provide project management support, task tracking, and stakeholder engagement

SOLUTION:

- Designed and implemented a comprehensive data integrity training plan, ensuring alignment with regulatory requirements and industry best practices, which detailed the curricula and course objectives
- Researched and incorporated concepts from all available industry and regulatory guidance to ensure alignment with current best practices
- Collaborated closely with subject matter experts (SMEs) to tailor course content, ensuring relevance, accuracy, and applicability to specific operational needs
- Developed over 20 customized training courses, addressing all topics outlined in the training plan as well as critical messaging from leadership
- Provided project management support, overseeing timelines, deliverables, and resources to ensure seamless execution of the training program
- Established a structured task tracking system, maintaining visibility on progress, dependencies, and milestones for efficient project completion
- Engaged key stakeholders and leadership throughout the process, facilitating alignment, feedback integration, and sustained commitment to training initiatives

KEY BENEFITS:

- Best-in-class data integrity training program
- Resolution of long-term corrective and preventive action
- Improved data integrity compliance profile
- Ensured satisfactory follow-up inspections



KPIs

- Engaged with over 40 internal stakeholders
- Developed over 20 courses covering 92 learning objectives
- Training delivered to over 9,000 employees
- Referenced 9 industry and regulatory bodies and over 24 standards

“[The team] set clear milestones and delivered quality work. They took the time to understand our specific needs and tailor their approach accordingly, ensuring that the solutions they provided were aligned with our business goals.”

- Principal GMP Data Integrity Specialist

CONTACT US

