

Establishing a Global Data Integrity Program for a Beauty Company

This client is a worldwide manufacturer, distributor, and marketer of cosmetic products in the health and beauty industry who had identified that data integrity was an area of concern. The client had hired a retired regulatory industry expert to assess data integrity within their company, and an initial audit at one facility identified numerous shortcomings. With this initial audit report in hand, the client contacted Clarkston to assist in addressing the data integrity issues identified.

This effort began in the areas of Research & Development, but quickly spread to other areas of the business, including IT and Global Supply Chain. Clarkston provided action plans and timeline estimates to the business to help prioritize and synchronize the work, leveraging our experience and building block methodology to put documentation in place in a streamlined and structured manner. After putting plans in place across the different areas of the business, the Clarkston team began drafting various documents to address the audit findings. In many cases, processes and procedures were non-existent, and Clarkston worked with the client to identify key actions and responsible parties to put the necessary procedures in place. In some cases, this represented a significant lift to bring groups of more than 20 individuals together to design processes and train the business.

As the project continued and audits persisted at other facilities, Clarkston helped coordinate the remediation efforts with client team members from around the world.

Consumer Products Case Study

PROJECT OVERVIEW



INDUSTRY:



Health & Beauty

PRODUCTS AND SERVICES:



Cosmetic Products

PRIMARY OBJECTIVES:

- Develop processes, procedures, and trainings
- Manage site remediation efforts
- Increase data integrity compliance in the Commercial, IT, and Supply Chain areas of the business

RESOLUTION:

- Met with client to determine, review, and prioritize business needs based on preliminary audit findings, where approximately 175 initial findings were identified
- Developed action plans to identify how to address the various findings and assign topics to select team members
- Ensured that data integrity was captured according to ALCOA+ standards
- Interviewed business contacts to understand current processes and formally document them in procedures
- Collaborated with business leaders in R&D, IT, and Global Supply Chain to resolve issues on a global level and ensure that individual findings at local levels were also resolved
- Authored or reviewed ~340 SOPs across numerous topics, including asset management, change control, clinical studies, compliance, computer systems, contract testing, data management, documentation, forms, lab audits, lab equipment, lab instrument qualifications, lab methods, lab processes, lab sample handling, lab waste, QA audits, regulatory requirements, security, shipping, training, and vendor management
- Ensured SAP access privileges would be maintained as users change departments or leave the company

KEY BENEFITS:

- Addressed significant shortcomings in client's data integrity program for seven different company sites across R&D, IT, and Global Supply Chain
- Better prepared client for regulatory inspection with a focus on data integrity
- Established data integrity as a focal point for the client
- Trained all R&D, IT, and Global Supply Chain employees on data integrity as a part of both new hire and refresher training

KPIs

- Authored or reviewed ~340 SOPs, process, or guidance documents
- Supported global data integrity program across seven sites to help ensure site compliance and readiness for data integrity audits