

CASE STUDY

Pharmaceutical Manufacturer

Compliant Laboratory Information Management System Increases Business Efficiencies

Challenge

This pharmaceutical company needed to establish a Laboratory Information Management System (LIMS) to more efficiently run laboratory operations and enable better business decisions.

Solution

Implemented a fully validated Part II compliant LIMS, including the creation of standard operating procedures (SOPs) for a LIMS environment.

Benefits

By achieving regulatory compliance, the company is now able to:

- Make more accurate and timely business decisions based on reports generated by LIMS
- Reduce the amount of time that Quality Assurance (QA) spends reviewing each batch prior to release of finished product

Challenge

This pharmaceutical manufacturer had not established a Laboratory Information Management System (LIMS); they were using an inefficient paper based system. The lack of an electronic data storage system impacted the company's ability to effectively manage laboratory operations and make informed business decisions. The situation was compounded by increased focus from the Food and Drug Administration (FDA) on electronic data storage regulations. The FDA demanded that the company become compliant with Part 11 compliance guidelines. Clarkston helped the company meet FDA Part 11 guidelines, which greatly increased their ability to optimize the efficiency of their operations.

Solution

Clarkston Consulting implemented a fully validated Part 11 compliant Laboratory Information Management System (LIMS) to increase laboratory efficiencies and maintain regulatory compliance.

Clarkston structured the project team to include an extended user group and key stakeholders to ensure that all appropriate business requirements were met and to achieve buy-in by users of the new system. Then the Clarkston team worked with the client to define computer validation procedures that would ensure the highest levels of product quality and meet FDA requirements.

During the project, Clarkston designed custom training materials and a rollout approach to address change management issues. The team also helped the client create standard operating procedures (SOPs) for LIMS.

Benefits

After implementing the new system, the client's management could make more accurate and timely business decisions based on reports generated by LIMS. This also significantly reduced the amount of time that Quality Assurance (QA) spent reviewing each batch prior to release of finished product. In addition, the client:

- Increased the timeliness of information received by end-users
- Reduced system complexity, which allowed users more efficient use of the system
- Increased site-wide Part 11 compliance
- Mitigated the risk of additional regulatory action by addressing the FDA's concerns

Company Profile

This client is a contract pharmaceutical manufacturer of both sterile and non-sterile products and a leading producer of pharmaceutical products, performance materials and industrial chemicals. The company has 20,000 employees globally.

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