LABUR

Implementation QA

Multi-System Implementation and Quality Management for FDA-Regulated Pharmaceutical Company

Validated pharmaceutical end products through multi-system quality management implementation to ensure FDA compliance for a global pharmaceutical company. The new quality management systems properly tracked deliverables to company processes, allowing for better oversight and management.

Client Profile

FDA-regulated global pharmaceutical company

Business Challenge

An international pharmaceutical company with multiple plants had several manual processes in place, including hand documentation, Excel spreadsheets and Microsoft Word documents to report and track events, including defects and lab incidents. The inefficiencies were impacting the company's ability to validate end products and was threatening their compliance with FDA regulations.

Project Overview

A multi-project, multi- quality management systems implementation, including Corrective and Preventive Actions (CAPA) and qualified event module implementation, was integrated to streamline preparation for regulatory audits, supplier quality management, and FDA compliance.

Built-in data collection, document handling, notification and escalation features, as well as training and documentation management, ensured reports, including defect

reports and other related CAPAs, were routed for proper resolution, monitoring, and scheduling.

Delivered Results

LABUR's quality management systems implementation and guideline documentation and training streamlined cross-functional areas of the business to ensure FDA-compliance.

- Increased trust and satisfaction among suppliers and customers
- Reduced cost of compliance to the business, including documentation that had been previously done manually
- Elevated the pharmaceutical company's brand reputation and integrity through its improved quality management and compliance process and systems, strengthening their international reputation and export business

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