REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Production and Process Control

Client

Fortune 500

Industry

Biotech

Business Challenge

To identify and implement a solution to solve a missing parts problem.

Background

A Fortune 500 biotech company frequently had parts missing when assembling equipment for a campaign changeover, which led to expensive, last-minute part fabrication and concern about the potential for product manufacturing delays and loss of revenue. These near-miss delays caused tremendous stress for operations management. Additionally, equipment setup was performed exclusively from Process and Instrumentation Diagrams, and relied on employees remembering setup details.

Challenge

Regulatory Compliance Associates® Inc. was contracted to identify and implement a solution that would solve the missing parts problem. During the initial investigation RCA discovered that the process was not documented in a manner the met GMP requirements. The solution needed not only to solve the missing parts issue, but also to create GMP documentation, demonstrating the process was in control.

Approach

After a thorough investigation, RCA created a process which included build lists, SOPs with color pictures embedded, and 3-D exploded diagrams for all setups. Additionally, all equipment parts were laser-etched with part numbers that corresponded to all documentation. Sealed containers were used to store parts for a specific campaign. Extensive training was performed and continuous improvement metrics were established to ensure the program continued to be successful.

Result

Missing parts prior to setup has been eliminated. Documentation meets cGMP regulations, and is being used as a training tool, which reduces the risk of relying on tribal knowledge. Campaign changeover times have been reduced by a minimum of two days, and in some cases six days, resulting in a cost reduction of $4 million per year.

"RCA took a crisis and turned it into a best practice"