

Creating Operational Discipline to Support Quality Initiatives

Client

Health Care Company

Industry

Medical Device

Business Challenge

Development and applying operational improvement plans along with a tracking system for operational tasks.

Background

A global health care company received an FDA Warning Letter for quality issues with its manufacturing facility. As the organization began working through the issues identified in the Warning Letter, it became clear, even with good quality systems, improved operational execution was needed to sustain successful results. The operational improvements were focused in areas such as shop floor discipline / execution, facility housekeeping and maintenance, managerial focus on all levels and, most of all, assessing and attacking specific operational shortfalls within all the operational groups.

Solution

The manufacturing facility engaged Regulatory Compliance Associates® Inc. (RCA) to develop and implement a plan for operational improvements to support the evolving quality management system. This assessment and subsequent improvements involved needed support from the somewhat skeptical operations management group. RCA and the local operations management team worked jointly to assess the plant and identify gap areas needing improvement to support the quality initiatives.

RCA assisted the facility to develop and implement a tracking system to monitor operational tasks, ongoing process improvements and ways to enforce accountability of key personnel. This tracking included key performance metrics for the following areas: training compliance, floor audit performance, batch record error improvement, document timeliness and line clearance performance. Recognizing that the operations management team was inexperienced, RCA engaged and mentored the key operations floor managers as they began implementing improvements and tracking progress.



Result

Besides crafting and implementing the operations improvement plan, RCA assisted the company to instill a culture of operational excellence and individual accountability with an inexperienced team. RCA helped the organization recognize gaps, develop action plans and create a tracking mechanism to monitor operational progress. Not only did these actions clearly improve quality and compliance, but they provided financial returns such as a deviation and inspection cost reductions as well as increased available line time which more than covered the cost of RCA's third party support. Most importantly, the management team learned the importance of communication across all departments and at all levels to achieve success. Ultimately, the facility's commitment will contribute to an environment of sustainability long after the RCA consultants have left.

“RCA helped the organization recognize gaps, develop action plans, and create tracking mechanisms to monitor operational progress. RCA raised the bar on operational discipline and feedback.”