Validation Enhancement at a Medical Device Contract Manufacturer

A major medical device manufacturer was experiencing quality issues in the field and receiving an increasing number of complaints related to products manufactured for them by a supplier in Mexico.

The client engaged Tefen to structure and lead a Process Excellence program aimed at improving their supplier's validation processes. The goal was to identify weaknesses within validation processes and formulate action plans to close the identified gaps, which ultimately strengthened the supplier's validation system.

Challenge

The challenge lies in identifying improvements, which can be made to the supplier's already compliant validation system. The customer does not want to just replicate its validation system at the supplier site, but to ensure the supplier's system is:

- Compliant with FDA requirements
- Simple, effective, efficient, and sustainable
- Mutually agreed to by supplier and the customer

Both parties realized that improvements could be made to the supplier's validation system, but time, project prioritization and resource constraints made it difficult to coordinate an effort which would solely focus on validation system enhancement.

How Tefen Helped

The customer and supplier jointly sponsored the project and assigned the necessary resources to support the analysis and design phase. The teams followed a comprehensive methodology to ensure no opportunity was left behind. Extensive process mapping of the validation system and sub-systems ensued.

Key activities included:

Segment Differences – Identified opportunities and placed them in to one of three segments; Gap (items that needed to be addressed), Observation (process differences with no action required), or Action Item (specific tasks to be performed by team members requiring an action plan).

Data Analysis – The teams gathered and analyzed historical validation performance data to: indentify causes of rejection, flag specific validation examples for further review, and to develop the performance metrics baseline.

Examples Review – "Walked" through past validations to explore gaps and catalogue additional improvement opportunities.

Review and Brainstorm – The team reached agreement on all gaps, segmentation assignments, and developed the targets for the future state.

Action Plan Creation – The team developed plans to address all defined Action Items and Process Gaps, including a prioritization and effort classification. The final "Gap Action Plans" contained all necessary details required for implementation.

Performance Excellence Delivered

Three months after the implementation, the supplier was able to increase First Pass Yield for validation protocols by 47%. Cycle Time improved by 58% leading to a 95% completion rate within 5 days. In addition, the team gained a deeper understanding, appreciation, and insight into each others' validation systems which will improve communication and cooperation of the parties involved.

About Tefen

Tefen is an international management consulting firm, committed to improving overall operational effectiveness for Fortune 500 companies around the world. The firm's main areas of focus include operations excellence, manufacturing, quality, customer service, research and development and supply chain management. With its "hands-on" approach philosophy, the company has achieved tremendous success in delivering quantifiable and value-driven results for its clients in a variety of industries, including healthcare, life sciences, general manufacturing, high-tech and financial services. All of Tefen's support programs are ISO 9001 certified. Tefen currently employs over 300 professionals worldwide.

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