



Re-engineering Product Complaint Handling for a Global Medical Device Manufacturer

Our client is a global medical device company providing products for use in Oncology, Pain Management, Cardiology, and Radiology. In order to serve their clients with the highest quality products, the client's understanding of customer complaints was vital.

Challenge

The FDA focuses on companies' complaint handling processes and systems to ensure that product issues which affect users are documented, and corrective and preventative actions to rectify these issues are taken when appropriate.

Working side-by-side with the client, Tefen performed a scoping assessment to establish a baseline of the company's current performance at two of their Complaint Handling sites. Based on the assessment, Tefen was able to gain further insight into the client's operations, the challenges they face, and then make an estimate of what the client could expect from the re-engineering efforts.

This assessment included preliminary data analysis, observations, and interviews with key personnel to gain an initial understanding of the major constraints limiting the sites from quality performance and dissatisfaction for employees and customers.

How Tefen Helped

Tefen and the client identified a list of goals they wished to realize after implementation. These included standardizing the complaint handling process and developing management support tools.

The complaint management processes were standardized by creating work stream management tools and performance metrics to monitor daily performance. In addition a staffing model was used to understand the appropriate staffing ratio at the company's facility to handle demand. A proactive communication line between facilities to allow efficient and timely complaint closure. In addition, Tefen developed and refined quality and productivity metrics for the client's suppliers to reduce risk.

In order to create sustainable change at the client site, management support tools and training on utilizing data to plan by prioritizing and managing daily investigation workloads implemented. Inevitably, this allowed the company to develop a standard process for determining proper investigation protocols based on complaint criteria.

Performance Excellence Delivered

The Tefen/Client team successfully implemented changes leading to improvements including:

- Reduced the number of open complaints from 4405 to 2339 (47% reduction)
- Reduced the number of open investigations from 1168 to 1002 (15% reduction)
- Designed standard queries and reports to track daily management activities
- Implemented standard tracking of employees and quality across all divisions
- Suggested improvements to streamline complaint handling process with suppliers

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.

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