



Complaint Management for a Global Medical Device Manufacturer

Challenge

Our client is a global developer and manufacturer of medical device products that was experiencing issues managing customer complaints in a timely manner. Two reasons for this were lack of ownership and definition of the complaint process. The client wanted to be able to improve their processes and provide high quality feedback to customers.

How Tefen Helped

Tefen used a phased approach to improve the client's complaint handling processes. In the scoping phase, Tefen worked with the company's resources to establish the current state of operations and identify the key areas to improve upon. These key areas included:

POR Flow: The client's current POR Process had 10 separate handoffs, most of which were non-value added. In addition, the entire complaint cycle took 60 days to be completed. Reasons for the long cycle time included: blurry images of the defected products from the physical investigation, time lag between the sample review and investigation, and the customized customer letters.

Organizational Alignment: During the initial analysis of the client's organization, it became clear that there was no sense of ownership over the complaint process, with limited QA coordinator knowledge. In addition, the complaint investigator's first concern was cycle time, rather than the quality of the response.

Process Definition: Tefen found that there were several issues with the client's current processes including: variability, priority issues were not followed, the CAPA definitions were unclear throughout the enterprise, and the root cause classification system was vague.

Technology Enhancement: The client's current technology was not up to par with the needs of the company. A customized response letter was created for each customer using Excel, automation capabilities were limited, and there was a large amount of hard copy letters that the resources had to sort through.

After the areas of opportunity were identified, an action plan was developed for each of the four levers, with a major focus on eliminating Non Value Added (NVA) activities from the processes.

POR Flow

Letters: The need for predefined customer response letters was apparent based on the amount of time spent creating new letters for each complaint. Tefen and the client defined what the letters should contain to maximize use.

Investigations: Instead of taking hand held pictures to capture defects, a tripod was purchased to allow clear focus on the defected product to minimize sample forwarding frequency.

Technology Enhancement

A web based POR interface was developed to allow customers to record complaints to alleviate the number of calls. In addition, a call routing process, which leveraged customer Emails, was created.

Organization Alignment

Ownership: To correct the lack of ownership, accountability was implemented into the organization through newly defined roles and responsibilities for the QA section.

Knowledge: A product defect checklist was created to drive customer interviews when reporting complaints. In addition, knowledge from previous investigations was leveraged to expedite customer complaints.

Investigations: A ranking system was established to order the investigations that came to the department.

CAPA: The process was defined and established throughout the entire department.

Performance Excellence Delivered

By eliminating performance inhibitors, the client realized:

- \$15,000 in cost reduction by eliminating non-value added activities
- Faster customer response time
- Reduced shipping cost by \$6,000 annually
- Elimination of 782 man hours of duplicate efforts
- Increased product claim knowledge
- 35% reduction in investigation cycle time
- Reduced response letter cycle time

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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