



Supplier Risk Mitigation in a Medical Device Company

Our client is a multi-billion dollar developer, manufacturer, and marketer of medical devices with more than 25,000 employees.

Challenge

The client received an FDA warning letter which resulted in the halt of new product releases to market. One of the key areas of concern identified by the FDA was the organization's lack of purchasing controls. The client needed to improve upon the quality and reliability of its supply. Tefen was engaged to employ process controls to hedge the direct materials supplier risk and assist with implementation throughout the organization. Tefen was engaged by the client to help with supplier risk mitigation strategy for their global procurement organization.

How Tefen Helped

Tefen facilitated a scoping with the client's VP of Operations, Supply Chain Director, Supplier Development Director, and the company's senior managers. During the scoping, several areas of the Supply Chain were examined to determine the current state, the future state, and the gap analyses including: Supplier Selection, Supplier Relationship Management, and Inventory Management and Demand Planning.

Supplier Selection

The purpose of Supplier Selection was to define and evaluate sourcing needs for components, materials, and services. Tefen developed a new purchasing process (which was integrated with the Design Review gates, Supplier Quality Assessments, and business requirements) to minimize the upfront risk when supply sources are profiled against the business and technological requirements. By completing this process outline, the client was able to prevent high risk components from being engineered into products without passing through defined supply chain review gates.

Tefen assisted our client by creating standardized evaluations forms, such as RFI (Request for Information), Supplier Quality Assessment, Technology and Manufacturing Assessment and Business Compatibility Review. Finally, a competency table was created to capture the various aptitudes of the current supply base, which fed into the supplier database, which captured supplier information, risk scores, segments, competencies, and component information.

Additionally, Tefen aided the client in developing a structured RFQ (Request for Quote) document to gather pricing, terms, and conditions prior to generating a Purchase Order or Supplier Agreement. Subsequently, supplier/development agreements were formed to outline standardized legal terms, conditions, agreements, and expectations. Tefen worked with the Materials Management Team and the client's legal department to define a Supplier & Development Agreement Decision Flow, which considers status of the supplier, NDA, and material spend to be used as new supply agreements are made, or when old agreements expired.

Our client had a large supply base of nearly 170 direct material suppliers, but no concrete methodology to differentiate between them. Tefen implemented a Supplier Segmentation process, which determined whether a supplier was a Strategic, Partnership, Business as Usual, Phase Out, or Not Recommended. These segments were utilized to drive Business Reviews and Performance Management metrics.

Supplier Relationship Management

Prior to the engagement, our client's suppliers were ranked based on three different tools. Tefen consolidated the three supplier tools into one, and created a second tool to decipher component risk. Each risk tool attribute, question, and parameter was developed alongside the supplier development staff and their Directors. Upon completion, an online web-application was developed for future analysis.

Supplier Relationship Management also encompasses Supplier Business Reviews and Performance Management. Based upon the Supplier's Segment, a standardized business review template and process was developed to encompass the Supplier's state of business, performance, technology, quality, and action plans. Tefen helped determine the topics, applicable segment, and frequency along with the standard template and process documentation.

Although our client was devoted to performance, a uniformed performance management suite was not constructed. The main supplier metrics tracked the quality of incoming inspected components. Tefen helped examine other aspects of the supply chain to create a fully-developed metric suite, which contained such areas as delivery, business, and inventory. From this, a visual supplier scorecard and graphs were developed so that a consistent message could be shared with the suppliers on a quarterly basis. An IT roadmap was created in order for the report and data analysis to understand the various gaps and future needs of the business.

Inventory Management and Demand Planning

Inventory Management was another focus for the client, because of significant losses occurring on the manufacturing floor. Tefen assisted in the inventory management process by helping to refocus the client's current cycle stock process to correct inconsistent counting frequency, missing inventory locations, and aligning counting strategies with the Finance, Materials Management and Manufacturing departments.

The next area is inventory visibility, which would allow the buyers to clearly determine what parts within QCRI pre-inspect were in process, on-Discrepancy, or pre-inspection. The final area was a visual pull system on the manufacturing floor with minimum and maximum quantity levels. Based on Tefen's implementation plan, the signal of shortage of materials would be direct from the manufacturing line, which would trigger the material inspection. These improvements allowed for a better management of the raw material in the inventory supply.

Demand planning coordinates all activities from Sales & Operation Planning through scheduling in order to decrease the variation between sales expectations, ships, and manufacturing build schedules. Tefen aided the client by forecasting and scheduling to maximize production efficiency, minimize inventory cost, align service levels, and minimize risk to production from supply. This was achieved by a Kanban replenishment system. In conjunction with this, a material master guide was developed to assist as a reference to complete the Material Master in SAP. The final development was a Component Shortage Analysis tool utilized by the schedulers to determine what manufacturing finished goods can be produced and when material would be obsolete.

Performance Excellence Delivered

Upon completion of the project, our client was able to see several overall benefits in their operations including: Minimized supply chain risk, increased product quality, streamlined supply base, shorter product development lifecycle, Inventory and material visibility, Standardized procedures, and inter-department leveraging.

In addition to the overall benefits, the client achieved benefits in their supplier selection, supplier relationship management, inventory management, and demand planning.

Supplier Selection & Relationship Management

- Defined Process flow that corresponded with the Design Review Gates based upon the stage of the component and the experience of the Supplier
- Well-written and qualified procedures, communication plan, and other documents
- Supplier Competency Table & Library Application
- Supplier Segmentation process
- Ranked 170 Suppliers Risk and 2000 Components

Business Reviews

- Standardized templates based upon supplier segment
- Consistent methodology for all direct materials
- Uniform graphs and communication of expectation for suppliers

Performance Management & Risk Tools

- A uniformed metric suite based upon supplier segments
 - A visual supplier scorecard
 - Process document
 - IT roadmap for report creation and data integrity
 - Well-defined risk attributes, questions, and parameters
 - Online web-application to control Risk Tools
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RFQ/Contracts

- Supplier & Development Agreement Decision Flow Tree
- Modularized Templates/Agreements
- Standardized language, terms and conditions of contracts

Inventory Management and Demand Planning

Inventory and Order Management

- Buyers had direct visibility into the various stages of QCRI inspection to allow for better managed inventory
- Cycle Count process and alignment with departments
- Visual Inventory Pull System Strategy with predefined minimum and maximum quantities

Demand Planning

- Kanban Replenishment system, process, and calculation
- Component Shortage Analysis Tool
- Material Master Guide
- Supplier Portal/EDI evaluation and selection

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.

For additional information, please contact:

Cristina Priamo, Marketing Associate

Tefen USA

(646) 652-8259

cpriamo@tefen.com

www.tefen.com

