



Global CAPA Implementation at Baxter Healthcare

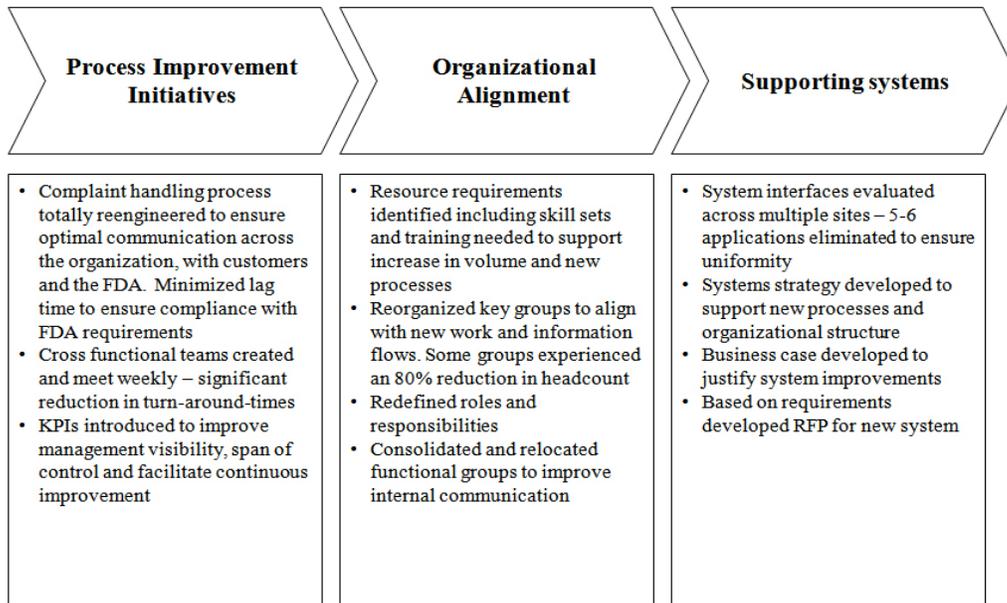
Our client, Baxter Healthcare is a multi-billion dollar a year company that develops, manufactures, and markets medical devices.

Challenge

An FDA assessment of Baxter's medical delivery division complaint process concluded that the length of time to handle a complaint in addition to the breadth and depth of complaint investigation was lacking. The FDA also required the client to follow a new definition of a complaint specific to life sustaining equipment. This would increase complaint volume ten-fold and as a result, stretch existing processes, organizations and systems to their limits. The client estimated that this level of compliance would add \$6 million in annual costs.

How Tefen Helped

Baxter engaged Tefen to re-engineer their complaint processes to reduce their annual expenses. To create a robust, standardized process across the 40 sites, Tefen mapped the current processes, organizational structures, and supporting systems at Baxter and then performed a gap analysis of the current processes. In addition, an internal benchmarking across several sites was conducted to develop best practices and key performance indicators to measure progress.



In addition, Tefen worked on:

- Consolidating the general office & manufacturing facility practices
- Developing a web based CAPA system
- Implementing TrackWise for Project Management
- Evaluating Quality sub-systems non-conformity processes evaluation
- Development of escalation processes for management review

Performance Excellence Delivered

After the implementation, Baxter had a standardized, global web-based CAPA system for 40 different sites. In addition, Baxter would only incur \$3 million in annual expenses. In addition \$1 million in annual cost savings were identified due to re-engineering efforts.

About Tefen

Tefen is an international management consulting firm, committed to improving overall operational effectiveness. 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.

For additional information, please contact:

Cristina Greenberg-Priamo, Sr. Marketing Associate
646-652-8259

