Lean Transformation Case Study in the Medical Device Industry

By Zeev Ahronson

1. Background

In the past, medical device companies have been reluctant to adopt the Lean philosophy. There were many reasons for this: strict regulatory requirements pose highest quality performances, the Lean approach was seen as a way of cutting corners, any non value adding activities were eliminated as options and companies were tied down by cumbersome QA and QC activities which are difficult to challenge. However, as competition increases in this fast-changing environment, all company departments are under pressure to keep control and continuously improve their time to market, costs, scope completion, reliability and quality. They are expected to act proactively and be aligned and synchronized to achieve the main business goals of profitability, on-time delivery, quality and customer satisfaction. General managers can no longer look at the company departments as independent silos, but need to apply end-to-end visibility to identify any, bottlenecks, delays, poor quality, and areas of inefficiency. Having a "Right the First Time" culture in place requires that all groups lead quality and efficiency enhancement initiatives, eliminate non value added activities, reduce costs and cycle times, and fully exploit the production and logistics infrastructure and facilities.

This holistic approach covers all main management processes, including goals and objectives, monitoring and control, process optimization, and overall collaboration. In this article, we take a look at Tefen's approach to a lean transformation for medical device companies.

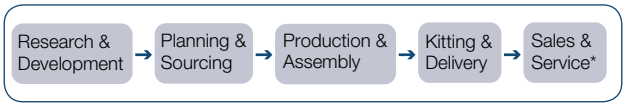
2. Cross Organizational Lean Transformation

Tefen's comprehensive approach starts with cross-organizational diagnostics to assess key factors:

- Business prioritization and customization of markets, customers and products.
- Strategic goals versus actual performance for gross margins, customer service, and performance excellence
- Operational practices in place – planning, monitoring and control, lean operation, continuous improvement, quality embedded along the entire supply chain
- Managerial aspects - optimal organizational structure, Key Performance Indicators and management routines in place
- Organizational culture of partnership, transparency and mutual collaboration

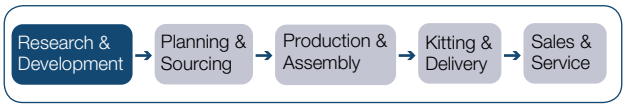
This assessment allows us to identify the main gaps which are preventing the company from achieving its strategic, business and operational goals. It reveals actual performance both within individual departments and secondly, as part of the company value chain, taking into consideration its interfaces and internal supplier-customer relationships.

Medical device company value chain usually look as follows:

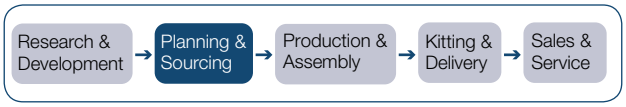


* Not included in this article

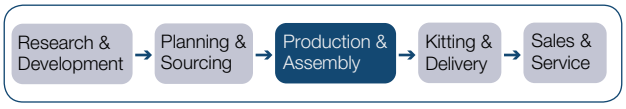
The main questions raised during the assessment with regards to the above mentioned elements included:



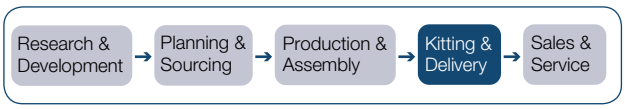
- Alignment between the company strategy and the R&D portfolio of projects
- Professional project management focusing on efficient resource allocation and milestone management, achieving cost and time to market goals
- Efficient R&D processes eliminating rework and quality issues
- DFX methodology in place ensuring development of mature products in aspects of manufacturability, assembly, serviceability, reliability, usability, cost, etc.
- Smooth and well planned transition from development to production



- Forecast management - weekly forecasts accuracy, interface and alignment between Sales and Planning departments through an S&OP (Sales and Operations Planning) process
- Segmentation into product types: Runners, Repeaters and Strangers, with a unique and dedicated planning policy for each type
- Optimal planning methods achieving maximum effectiveness of production facilities and workers availability
- Planning consideration of customer prioritization and service level agreements
- Supplier management policy and routines ensuring supplies arrive on time, at the best price from few sources



- Actual versus optimal performance survey looking at overall equipment effectiveness, products actually produced compared to the maximum plant capacity, minimum downtime periods, minimum transportation and inventory.
- Looking at the production perception – departments versus value streams, lines managing products along the production process from raw materials until finished goods, material flow across the production floor, maximization of value added activities over non value added ones.
- Management and performance of supporting disciplines such as logistics, quality, maintenance – transferring these disciplines from outside to inside the production chain, thus eliminating waste, waiting time, and WIP (Work In Process)
- Waste elimination through Lean principals: visual management, 5S, production line balance, shift replacement routines, and water spider (pushing the required materials to the production stations only when needed).
- Six Sigma elements in place resulting in minimum variance and maximum stability of the operational processes, including: statistical process control, root cause identification, continuous improvement.



- Optimal planning of the kitting and packaging activities to smoothly follow the production lines
- Ongoing monitoring and control over the kitting and packaging efficiency through a set of Key Performance Indicators
- Differentiation between packaging processes for finished goods to be shipped to customers and parts transferred to the warehouse
- Material pull flow optimization to suit the work rate and rhythm and respond immediately to customer needs and sales forecasts
- Efficient shipment planning and management, preferring sea over air shipment

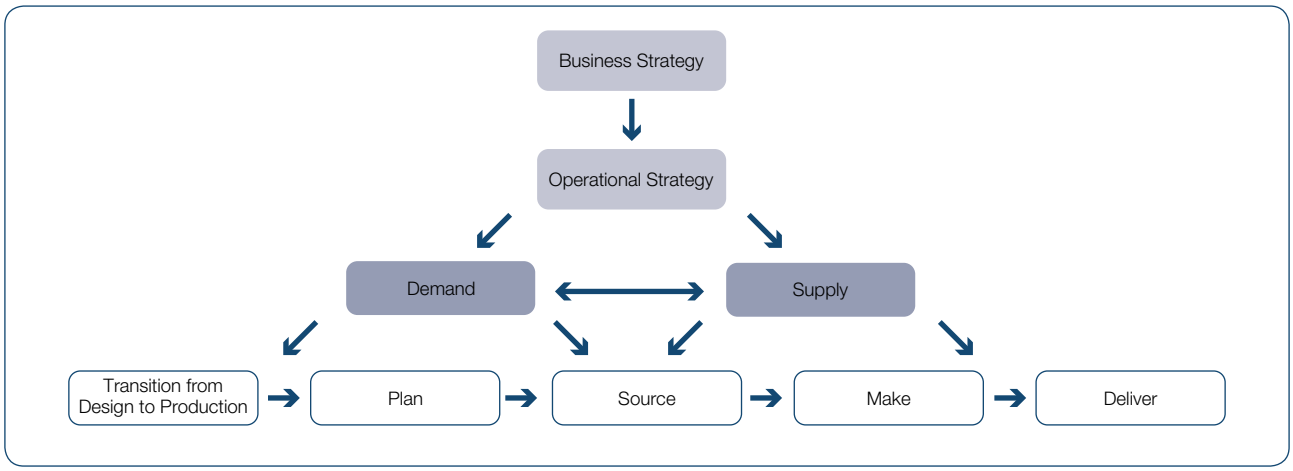
By using a multi-level and holistic diagnosis across the company value chain, organizations receive a drill down of into specific performance issues that are hampering their objectives, revealing root causes for main problems, and providing practical recommendations to impact their future performance.

CASE STUDY

1. Introduction

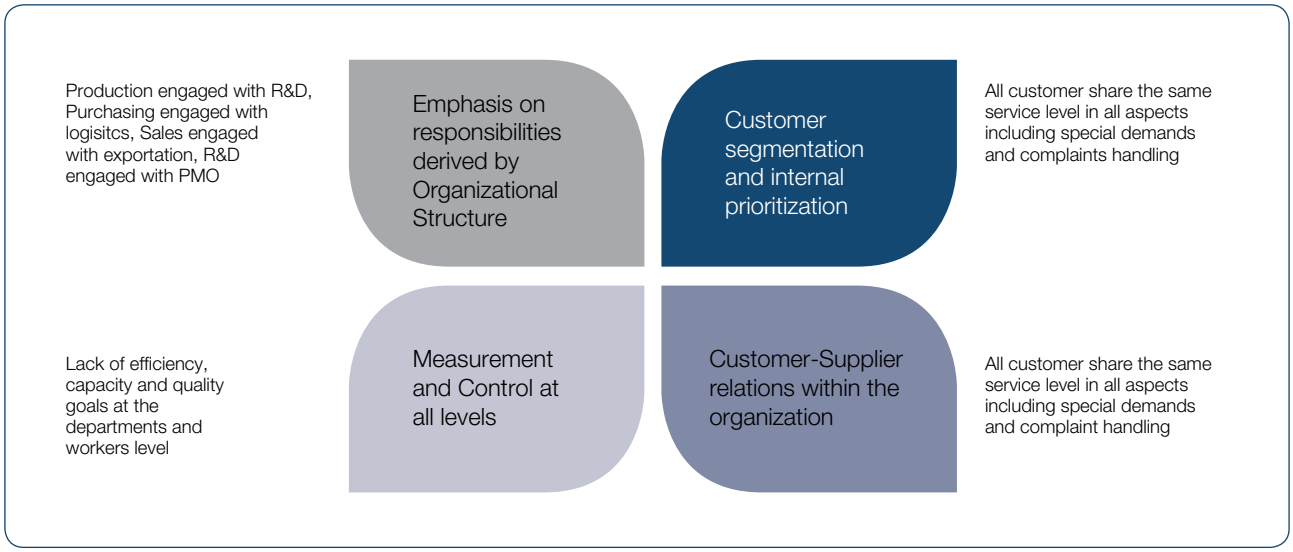
During 2013-2014, a world leading medical device company, facing a few challenges related to new product ramp ups and a new operative production site, started a concentrated effort to improve its production and supply chain efficiency, quality and on-time delivery.

Tefen was asked to perform a diagnostic survey across the company supply chain starting from the New Product Introduction, going through Planning, Sourcing, Production, Logistics, Quality Control, Quality Assurance, and ending at Delivery.



2. Assessment

The diagnostic process revealed some common issues at the company:



To examine the various elements of LEAN, Tefen used its LEAN Audit questionnaire:

2.0		Level 1	Level 2	Level 3	Level 4	Level 5
LEAN Leadership	Leadership	■ Leaders Occasionally make visits to the facility floor ■ Facility leaders sometimes show characteristics of a few of the CI Mindsets but are not consistent in demonstrationg these. ☐	■ Leaders make visits to the facility floor at least once per week ■ Leaders visit some of the performance dialogue meetings ☐	Leaders make visitits to the facility floor 3 or 4 times per week. ■	Leaders demonstrate all CI mindsets on the shop floor every day ☐	Leader manage the citical lean processes, and act as a role model. ☐
	Leader Standard Work	There is standardization on how LSW is developed. It is performed infrequently There is no tracking to check if LSW is performed ■	It is performed daily, and there is about 25% compliance. But, there is no tracking to check if LSW is performed. ☐	■ LSW is developed for all levels of site leadership ■ It is performed daily, and there is about 50% compliance. ☐	It is performed daily, and there is about 75% compliance. ☐	■ Checks are executed at critical points in the process where weaknesses or known points of breakdown are possible ☐ ■ It is performed daily, and there is above 90% compliance
	Coaching and Feedback	Some leaders have begun to provide specific coaching and feedback ☐	Facility leaders occasionally allocate time in their agenda to provide coaching and feedback to direct reports ■	Facility leaders have specific times in their agenda to provide coaching and feedback to direct reports. ☐	The three culture management tools (Feedback, Storytelling and Recognition) are being integrated into many leaders' team meeting structures ☐	■ All the leaders have specific standard work to provide coaching and feedback to direct reports ☐ ■ The three culture management tools are integrated into every leader's team meeting strucutre.

3.0		Level 1	Level 2	Level 3	Level 4	Level 5
Standard Work	Job Instruction	■ There is little standardized process on how to do job tasks. ■ There is little standardization of tasks across crews ☐	■ Most learning takes place on-the-job, and most tasks are not standardized across all crews. ■ There is no defined plan in place for fully implementing Job Instruction (JI) training. ☐	■ Some critical tasks have been standardized across all crews ■	■ Leaders created Job Breakdown Sheets for most critical jobs ■ Leader provide JI based training to all employees who need to be trained on critical jobs ☐ ■ Most critical tasks have been standardized across all crews	■ JI methods are used for training consistently throughout the entire facility ■ All critical tasks have been standardized across all crews, and Job Breakdown Sheets developed for these tasks ☐
	Leader Standard Work	■ Some Standard Work documentation has been created. ■	■ Standard Work is set for all major processes ■ Standard Operating Procedures (SOP's) are consistent in content & structure. ☐ ■ New employees are trained using the Standard Work	■ There is a process for updating standards ■ There is an audit tracking system for SOP compliance ☐ ■ Each SOP specifies content of the work, optimal sequence of steps and target output of the work	■ At least 30% of critical tasks have a SOP ■ Each SOP specifies content of the work, optimal sequence of steps, timing to complete and target output of the work ☐ ■ It is evident critical tasks are executed	■ 100% of critical tasks across the facility have a SOP ■ Standard work KPI is being manged ■ Continuous improvement of standard work are drived by innovations and input from workers, engineers and managers ☐

■ Filled in bullets specify the organization level at different Lean categories.

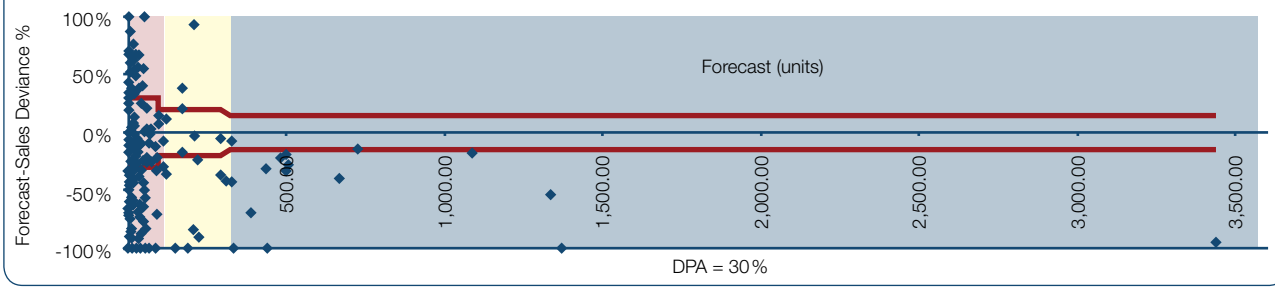
The outcome of the LEAN audit indicated some significant gaps in LEAN infrastructure and management at the organization:

Lean Audit Results

Sales forecasting

Sales forecasting was delivered on an annual basis. The accuracy of the forecasts for each month revealed that the monthly DPA (Demand Planning Accuracy) metric performance was only 30%. This poor accuracy environment meant that huge inventory volumes were required in able to supply customer needs.

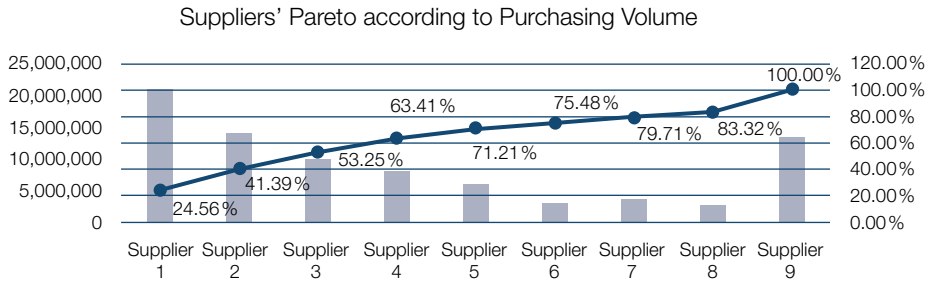
Divergence analysis between actual sales and forecast



Monthly forecasts accuracy is very low. High levels of safety stock is required to allow stable production planning.

An examination of sourcing and connected data analysis calculations showed a high dependency on sole source suppliers (which is more common throughout the medical device industry than in other industries), as illustrated below:

Strategic sourcing



3 suppliers are the source of 55% of the purchases volume

Very high volume of purchases from a limited number of suppliers

Production management

Moving on to production management, we noticed that all products are planned, managed and monitored by the same processes and means. However, our analysis found that only 10% of the products drive 90% of the company income. We recommended adopting a differentiation between Runners (high volume production and low variation in demand products), Repeaters (moderate volume and variation) and Strangers (low volume and high variation products).

Runners Group

- High Percentage of the production/sales volume
- Demand vaiability tends to be low

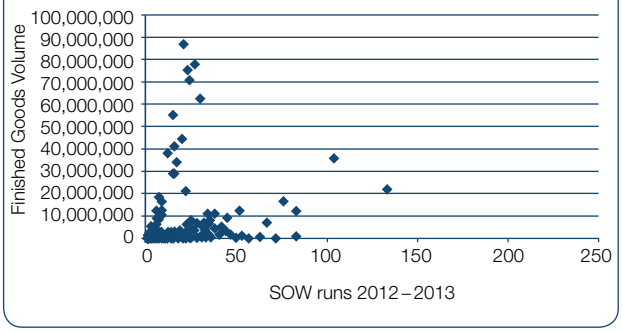
Repeaters Group

- Demand and production volume are moderate

Strangers Group

- Production frequency and volume are low. Responsible for most of supply chain noise

Comparison Analysis: SOW runs vs. Finished Goods volume –2012–2013



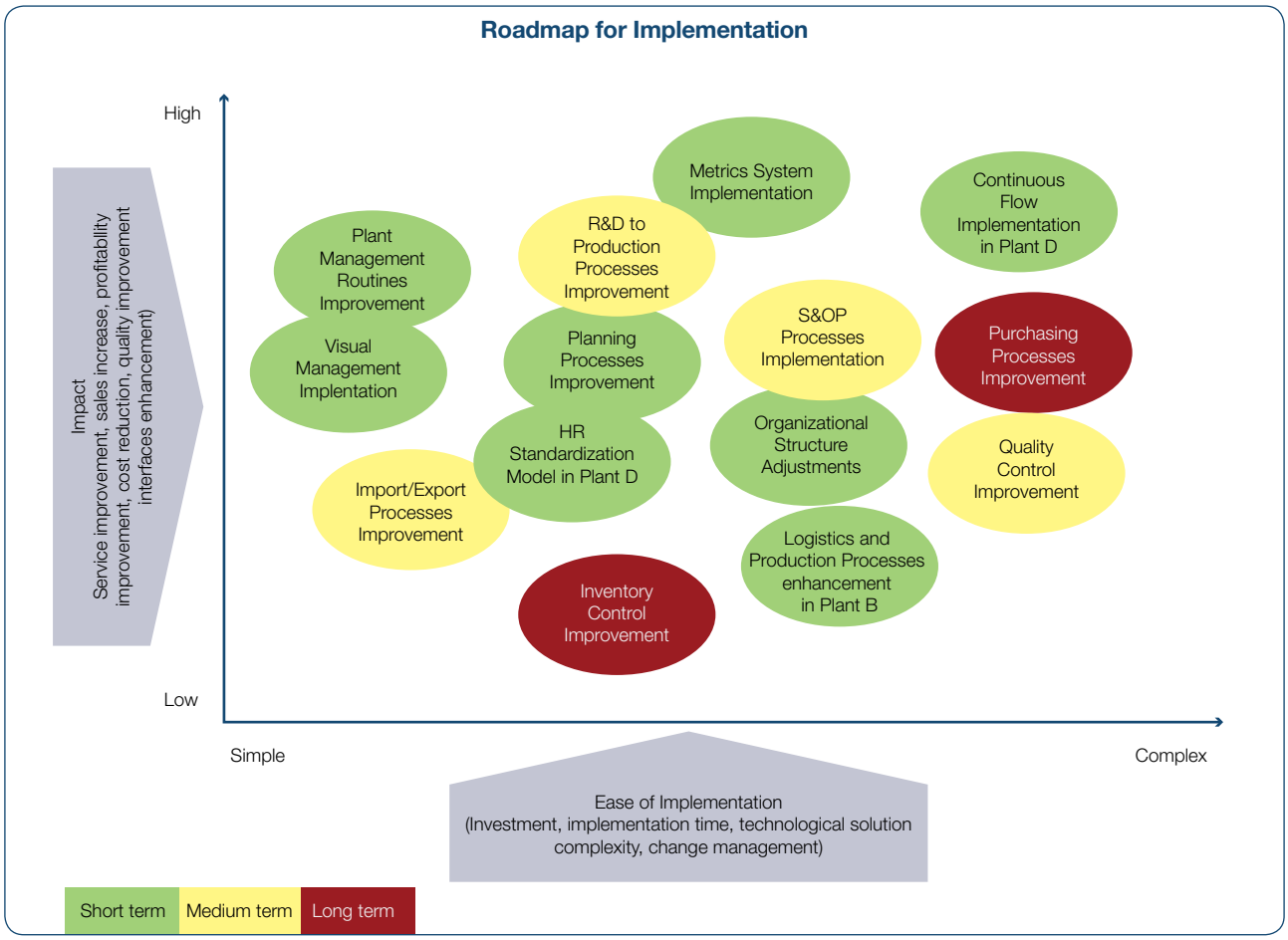
10% of the products drive 90% of the company income. For maximal operational effectiveness, assigning different product lines to different plants strategy is required

Measurement & control

The main Key Performance Indicators related to finance issues for which data was readily available. Very few operational Key Performance Indicators were in place, some of the existing KPI's relating to the supply chain operation were subject for disputes over the relevancy and benefit of producing them. Management routing and continuous improvement processes based on KPi's results were also missing.

3. Designing the vision

The diagnostic phase recommendations were evaluated according to impact versus ease of implementation as detailed below:



Brainstorming sessions to prioritize the recommendations lead to definition of an implementation plan comprised of six pillars:

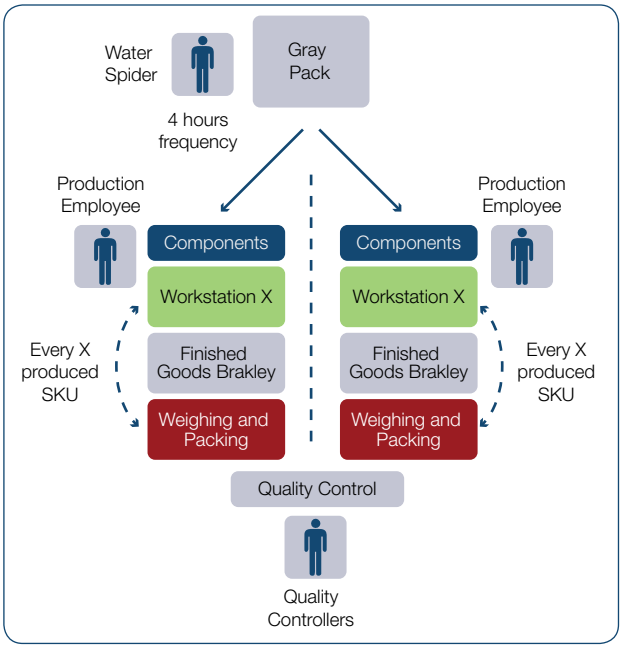
1. Robust planning & scheduling processes to steer the operation

a. Clearly prioritize customers, products and work.
b. Capacity modeling based on OEE, yield and resource utilization
c. Close interface between Sales and Production planning
d. Weekly work plan based on monthly forecasts, S&OP process and relevant KPIs of DPA (Demand Planning Accuracy) and MSA (Master Scheduling Accuracy)

2. LEAN operation along the supply chain elements to maximize income and profit

a. Well-defined interfaces throughout the organization to enhance “right the first time” performance
b. A designation of value stream factory lines to reduce lead time and WIP inventory and improve materials flow and PPC department planning ability.
c. Division of produced SKUs into groups with similar characteristics – similar machines/stations.
d. After definition of groups (the basis for future value stream lines): matching line configurations with lean principles, while minimizing unnecessary operations, product quality inspections and reduction of manual operations
e. Waste elimination through value stream production lines, WIP reduction and material pull systems
f. Quality elements embedded within the production and supply chain lines instead of a separate station consuming cycle time and WIP
g. Visual management and management routines involving all workers in the monitoring and control environment and continuous improvement culture

	Catalog Number	Machine #1	Machine #2	Machine #3	Machine #4	Machine #5
Product Group #1	111	✓		✓		✓
	122	✓		✓		
Product Group #2	211	✓	✓			
	222	✓	✓			
Product Group #3	311			✓	✓	✓
	322			✓		✓



3. Effective and efficient work processes to meet the organization’s business goals

a. Development roadmap addressing the business strategy
b. Sales forecasting process following customer product management strategy
c. Smooth transition from development to production using concurrent engineering principles
d. Effective and efficient production planning as part of the S&OP process
e. Production management processes focusing on on-time delivery and quality as well as OEE (Overall Equipment Effectiveness) and labor cost monitoring and control
f. Efficient supply chain processes, including strategic sourcing, purchasing, inventory management, import-export and shipment.

4. Aligned organizational structure and roles to improve flexibility and focus

a. Restructuring the Quality department to support organizational departments
b. Water spider roles responsible for pushing the required raw materials to the production stations only when needed
c. New continuous improvement roles built into the operation with responsibility for developing and implementing change.

5. Measurement & control systems to drive improvements

a. Defining a performance management infrastructure – dashboard, KPIs at all hierarchy levels, visual management tools and management routines.
b. Simple, compelling KPIs, aligned to value-stream performance (throughput, productivity, lead-time, plan vs. actual, percentage of deviations).
c. Continuous improvement based on the KPIs results at all levels

6. LEAN culture

a. Standard work in place including a daily 10-minute ‘stand-up’ routine, to review the previous shift’s performance by each analyst, raise operational issues to be resolved (equipment malfunctions, missing reagents etc), and make new plans accordingly.
b. Visual boards installed per team, to support communication of KPIs and plan execution progress.
c. Involve people more in their department performance, routinely raising improvement ideas.

4. Results:

Changing line configurations was accompanied by a change in the plant's operating perception, which included

- Organizational structure changes (quality, production, logistics, maintenance)
- Reduction of inventory, labor cost and cycle times
- Improved logistics operational method (using water spiders – distributers and diffusers of components/ finished products)
- Improving management monitoring and decision making through the implementation of line real time management routines and metrics using dashboards and visual management

In any lean transformation, it is not only important to implement the content-based work streams but also critical to manage the change process itself, both from the perspective of an organization and on an individual level.

The main change management tools used in this project were:

1. Stakeholder management – this activity was more important than usual, due to the high seniority of employees and their increased resistance to change. Major department managers, team leaders and key analysts were analyzed for their level of influence on others and their attitude towards the change.

2. Ongoing communication to all levels
   a. Communication of project progress through the daily and weekly meetings. The fact that each employee in the plant felt part of the change made the process a lot smoother.
   b. Plant management was involved and informed about the progress on a weekly basis during the management meetings.

Lessons learnt from Tefen's lean quality program
The key success factors for a well-established change in operation are:

- Management commitment and involvement
- Buy-in from team leaders and analysts
- Tight support in the initial stages of the implementation
- Implementation of pilot lines prior to roll out
- Creating robust management routines and KPIs and ensuring sustainability their sustainability

This project has been gaining an overall significant impact on the company, implementing a continuous improvement culture, through ongoing measurement and control as well as responsive management routines. Main operational KPI's have been improved reflecting 15% improvement in demand forecasting and 15% production efficiency improvement.
Project is still going on tackling all operational issues resulting in bottom line performance improvement

Zeev Aharonson, Partner, Tefen Israel