ISSN 1720-4003
ANNO 2 - NUMERO 4 2003

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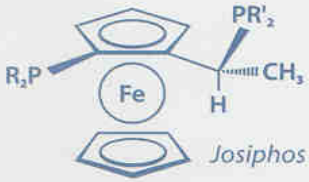

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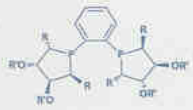
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The Lean Organization

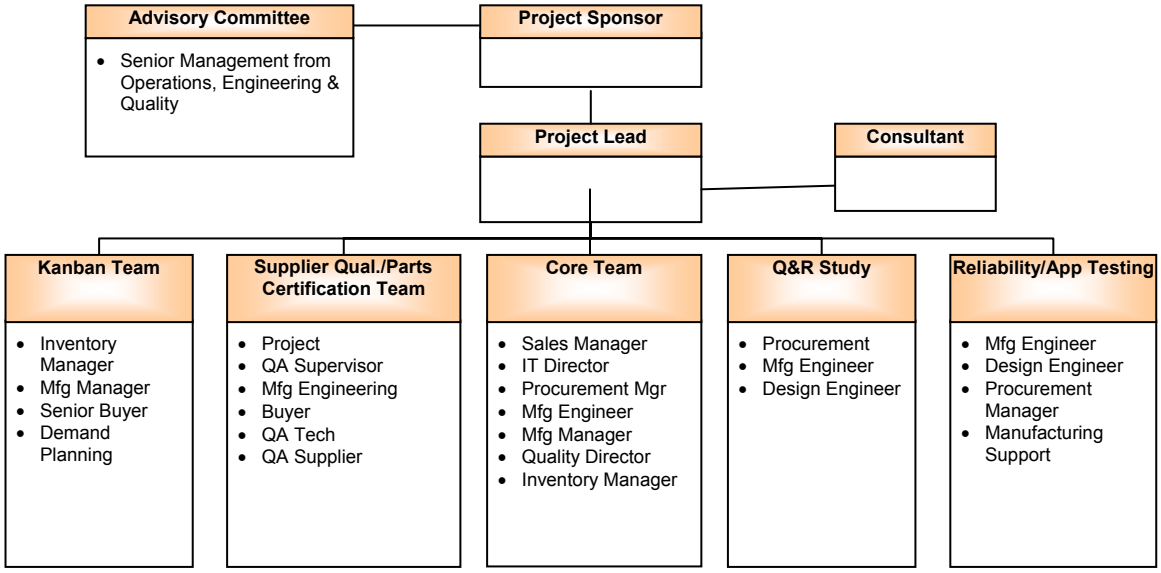
Supply Chain Redesign: *A Medical Device Company's success story in a regulated environment.* ***By Patrick Lucansky and Robert Burke***

A $125 million medical device company which manufactures medical sterilization equipment and sterilant supplies had realized the operation suffered from a common malady, strained resources. The organization had been growing at a rate of 13-17 percent annually over the past four to five years and needed to make process improvements to be ready for the challenges of the next five to seven years. A corporate quality program was active, as were a number of "tiger teams" attempting to improve product performance.

The organization's management and a dedicated general workforce were aware that several supply chain issues required attention. An earlier study revealed a functionally-structured operations environment in which purchasing, manufacturing, demand planning, logistics, design, and quality were disconnected. Partnering skills with suppliers lagged behind expectations. Supply chain excellence would be a critical factor in their future marketplace success. About 75-80 percent of the cost of goods sold was from suppliers. Of numerous SKUs, they only made ten. Given the lack of vertical integration, it was a materials game. Lacking adequate supplier and parts certification processes, management asked, "How do we develop a more robust supply chain?"

An Activity Based Costing (ABC) analysis demonstrated excessive material handling costs, excessive manufacturing lead-times, and many non-value added (NVA) activities. Inventory was unacceptably high, with four annual turns. Processes surrounding incoming inspection were sub-optimal, leading to WIP rejects (of 'A' items) in excess of 10 percent. Scrap and rework rates were abnormally high despite having ongoing improvement initiatives; they concluded a redesign of their supply chain was required. They established a cross-functional team shown in Figure A to map out the redesign process.

Figure A Supply Chain Project Organization



The core team was chartered to align the project's objectives with a methodology that was fact-based, process-driven, and consistent with their corporate strategy of enhancing value throughout the organization. Thus, the success of the project team required a strategic, long-term approach with incremental and meaningful tactical results. While it was critical to address the immediate need to reduce inventory and WIP rejects, the team looked to develop long-term objectives that provided a framework to manage suppliers. The project's mission focused on: 1) establishing long-term relationships with strategic suppliers, 2) receiving cost-effective, quality products in a Just-In-Time (JIT) manner, and 3) developing world-class suppliers. The team developed a plan of attack that consisted of collecting data, analyzing results, proposing redesigns, making a business case, and formally implementing key projects (see Figure B).

Strategic Partnering Begins

In the pre-analysis phase, the core team collected data and identified 20 percent of the components (50 components) that represented 80 percent of their material costs and inventory value. Coincidentally, 10 percent of these components represented 90 percent of all WIP rejects. This represented 50 key components on an estimated 15 percent of the bills of material (BOM) for two primary products. The team then identified 15 of the 110 production suppliers as potential candidates for strategic partner status. These suppliers were single-sourced, where substitutes, or alternates were difficult to find and strategically important. Also, these suppliers were good candidates for the strategic partnership because they periodically inquired as to their performance on quality, delivery, cost, etc. From a cost perspective, these suppliers produced the majority of components and subassemblies for the two primary products of the project.

Figure B Supply Chain Project Phases

Phase	Definition
1. Pre-Analysis Phase	Collect data, agree on meeting formats and timetables, and identify customer requirements.
2. Analyze Data and Information	Conduct cross-functional training, validate opportunities and benefits, value stream the physical and information flow in the supply chain, and prepare a reduction.
3. Propose Redesign	Develop "To Be" process maps, suggest supply chain reconstruction, develop an implementation plan, agree on performance measures, and agree on benefits and results.
4. Make Business Case	Define and present to senior management the cost benefits of the "To-Be" supply chain process. Scope the effort and timetable.
5. Implement	Start implementation and measure the benefits as they relate to other initiatives and bottom-line special requirements.

As the effort began to take shape, the selected suppliers were presented with the envisioned supply chain process and were encouraged to participate in a pilot program. Enthusiasm was mutual for this win-win approach. As they proceeded through Phases One and Two, the core group spent the first three months collecting data, mapping processes, defining customer requirements (internal and external), revising project plans, and securing people resources. They soon discovered that additional skills were required to support the process mapping, project management, and to some extent, data collection methods.

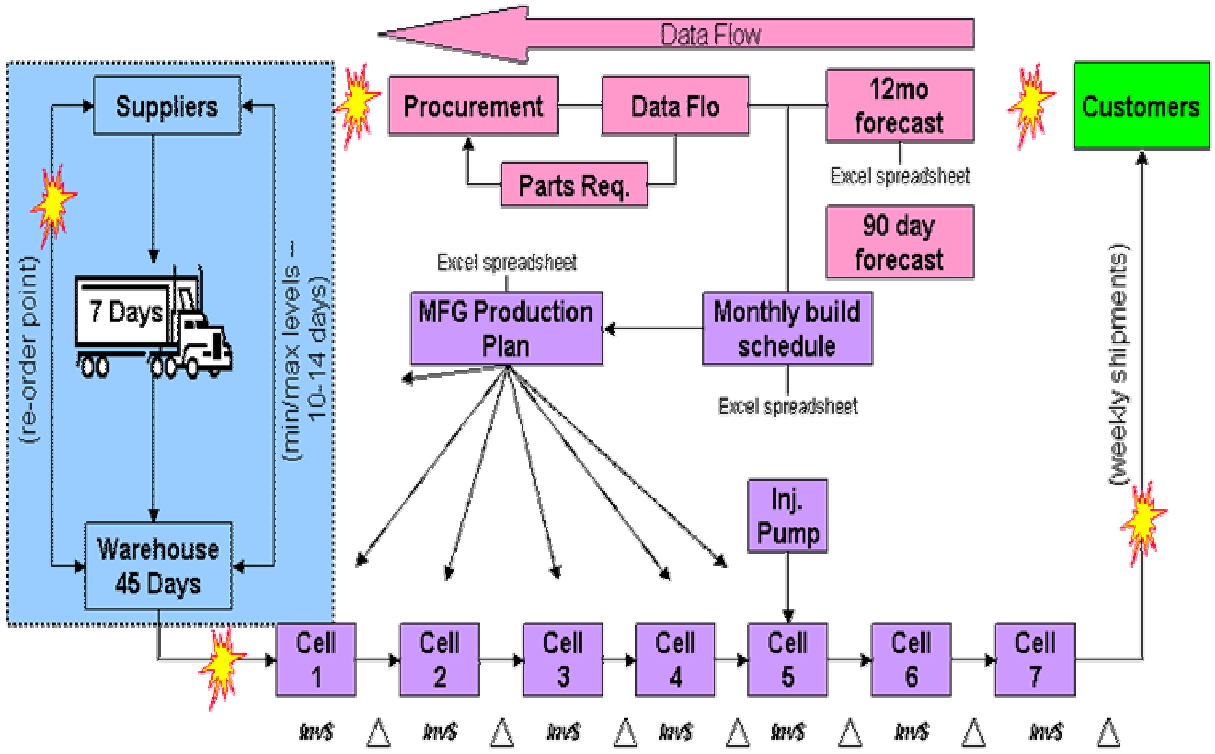
During the next three months, they focused on creating value stream maps for all major supply chain processes, reviewing the ABC analysis on these processes, clarifying customer needs and requirements, benchmarking against 'best in class' (in their business sector), and developing an implementation plan. The team gained understanding about various supply chain components, such as: what worked well/marginally, improvement opportunities and what level of improvement could be expected. They selected five distinct projects that met their short-term goals (reduce inventory and rejects) while staying focused on the mission to implement a long-term supplier management process.

Next, they began to implement the process improvements including: design and implementation of a Kanban-style process for ordering and delivery of the top 50 components and subassemblies, qualification of key suppliers, supplier certification of individual components and subassemblies, elimination of in-house inspection, introduction of lean techniques into the product design process, and review of the adequacy of test methods as performed by suppliers for selected components of the top 50.

Current State of the Production Area

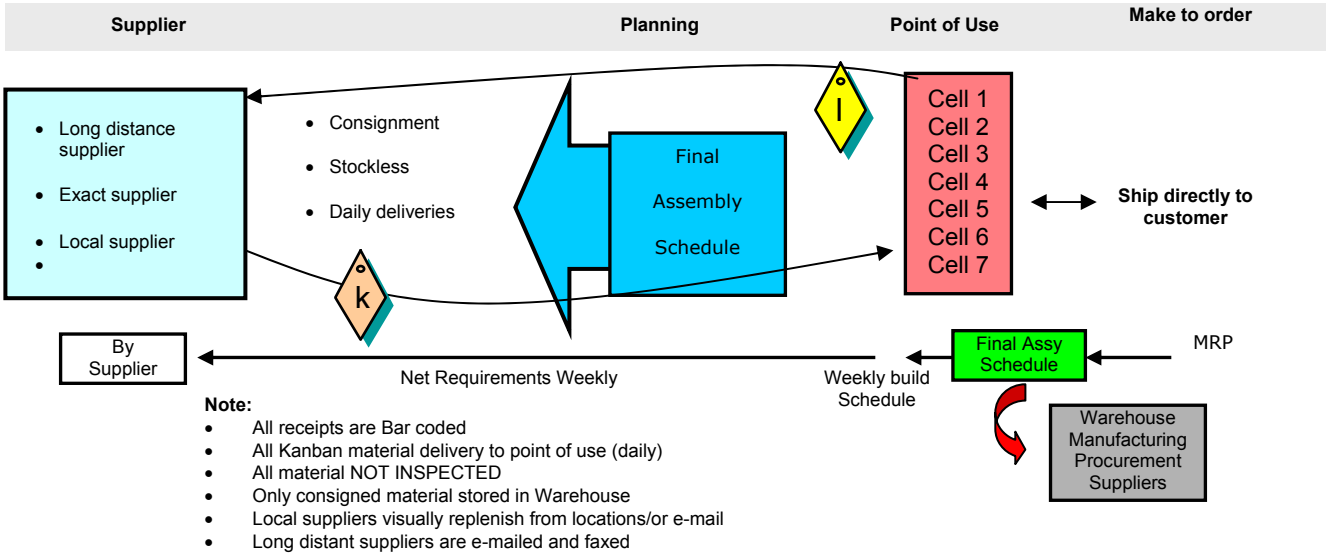
The production area was congested with raw materials while a warehouse held an estimated 50-60 days worth of inventory. Quality was below standards resulting in very high rework rates (internally and externally) and it was suspected there were high scrap rates; 10 percent of all rejects were of 'A' type items. Analysis revealed the incoming delivery process contained 35 steps, of which only two were value-added (VA). On the positive side, the initial analysis revealed that the manufacturing floor was clean and organized into work cells. Expense items (bolts and screws) were delivered directly to point-of-use, supermarket-style; standard assembly procedures and equipment were available in each of the cells. (See Figure C.)

Figure C As-Is Supply Chain Process



Implementation began by eliminating the staging areas, removing excess inventory and containers (anything greater than 'kanban' quantities) from the WIP area and labeling the remaining containers. Floor space to accommodate only two days worth of production inventory was marked with tape, and deliveries of all material not authorized via a weekly schedule were stopped at the receiving dock. Ten of the top 50 items and five of the 15 key suppliers were selected to pilot the redesign processes.

Figure D Streamlined pull replenishment (KanBan/Consignment) model where NVA activities have been removed, lead-times/inventory levels were dramatically reduced and key process steps were documented



Supplier Selection/Qualification

The existing supplier selection/qualification process was ineffective and required a complete redesign centered on six principal areas.

Step One was reviewing the current supplier quality documentation and procedures. After a careful examination, only a few procedures and audit forms were retained.

Step Two was designing policies, objectives, procedures, tools, and techniques that supported the strategy to strengthen their relationship with key suppliers.

Continuing on, the following was developed and documented as part of their Supplier Quality Manual:

A. Define the Supplier Qualification Process: vision, goals, strategies, and techniques; continuous improvement; mutual customer/supplier expectations

B. Create a Supplier Certification Team: Develop cross-functional group consistency among procurement, quality, manufacturing, and engineering; define roles and responsibilities

C. Develop Supplier Selection Process: assessment format and category; feedback process; data collection and trend analysis

D. Develop a Supplier Rating System: rating system, audit process; review process/de-certification

E. Develop Supplier Performance Measures: quality index; customer satisfaction index; corrective action process; process improvement process; total cost requirements

F. Document Projected Benefits: profit sharing; information sharing; technology sharing; open communication; more business; concurrent engineering and value engineering.

Step Three, the Supplier Qualification approach was communicated to their 20 top suppliers at a two-day Supplier Conference. Supplier feedback was positive regarding the revised supplier requirements concerning quality, parts certification, and JIT delivery.

Step Four, an on-site supplier assessment was performed on the five suppliers which agreed to participate in the kanban pilot. A cross-functional team handled scoring and supplier categorization and documented new areas of opportunity.

The President of one supplier, commented, "We appreciated the supplier assessment feedback. It helped identify areas for improvement that will make us a better supplier."

Step Five, a system was developed for monitoring on-going delivery and quality performance against requirements. The system included a schedule of formal checkpoints. ***A President and CEO of another supplier stated, "I am very happy that they scrapped the former 'min-max' approach and adopted a Kanban method to pull material. It fits well with our own JIT approach."***

Step Six, a foundation for ongoing, periodic training in lean thinking and continuous quality improvement was set into place in *Step Six*. They employed "Lean Business Simulation™" workshop which effectively presented concepts, tools, and metrics with a learning medium of active participation. The exercise underscored how process improvements translate into bottom line savings, aligned vision with short- and long-term objectives, and bridged lean concepts with the approach to supplier management.

Parts Certification

A critical link in the supply chain was the assurance of quality parts being received from suppliers. Given the high rejection rate of WIP resulting in high rework and scrap rates, as well as the non-value-added aspect of incoming inspection, the project team looked for needed change. Since they designed many of the major components and subassemblies of their products, testing is considered an important part of the design continuum and is required by the U.S. Food and Drug Administration (FDA). The question facing the team was whether 'supplier performed' parts testing met the requirements for design specifications for all parts submitted to the FDA. If so, could they eliminate the incoming inspection and testing currently being performed on all parts being received?

The first step was to develop a procedure to review the product specifications and characteristics, all test requirements, packaging and handling specifications, and processes under SPC control, as well initiating a standard of five consecutive deliveries without incidents to qualify parts for certification. The second step was a historical review of component reject rates, corrective action trends, costs, and components critical to quality regardless of cost or rate of failure. A priority list for components requiring part certification was developed. The last step was a joint effort where suppliers reviewed the entire supply chain, assessed critical data, identified trends, and implemented corrective action.

Quality and Reliability Study

A gap analysis of the product design process demonstrated a lack of lean tools and a robust cross-functional involvement of the supply chain functions. Late supplier involvement in the design process was affecting product quality, cost, and cycle time to market. Areas of opportunity for consideration were: value engineering, supplier Failure Modes Effects Analysis (FMEAs), Design of Experiments (DOEs), Critical to Quality (CTQs), first article inspection, test, design capability, Design For Manufacturing (DFM), kanban deliveries, and a robust make/buy methodology. The ties and involvement with the product design process are still under review.

On the component level, a review was undertaken to determine what portions of the redesigned supply chain could be linked to the product design process. Several areas became apparent. First, suppliers had improved their ability to deliver raw components directly to their point-of-use. Second, what they learned about their suppliers' processes and capabilities made it evident that supplier interaction early in the design process would have a favorable impact in reducing lead times and product costs.

Application Test

Using the six problem components identified during the analysis as a vehicle for reviewing the adequacy of component testing, the following was revealed:

1. Test equipment at supplier sites was not being utilized.
2. 72 percent of the rejects found (from the six problem components) were caught and rejected at final assembly and application test.
3. Poor piece-part control process.
4. Inadequate test specifications at supplier sites.
5. Insufficient supplier corrective action processes.

A review of the organization's integrated testing and corrective action process is currently being performed. A design for quality methodology is being drafted to incorporate it into the product design phase. New producibility checklists will benefit two new products coming to market realization. Individual performance bonuses are now related to quality and reliability improvements for specific products (finished equipment and spares) where the company hopes to grow market share. Their challenges include data collection and analysis improvements, identifying the reasons why components work in one machine and not in another, and the ability to implement processes improvements faster to satisfy their affiliates and customers.

Summary: Vision and Commitment to Long-Term Improvements

The organization started by shaping their vision of supply chain redesign, consistent with their overall business strategy to provide value. They initiated a project that dealt with their immediate inventory and quality issues, while staying focused on the primary objective to implement a long-term, meaningful, mutually beneficial supplier management process. Their efforts dovetailed with corporate lean initiatives designed to cut inventories 25-30 percent, which they easily met.

The team successfully completed the most prolific cross-functional project they have ever undertaken. Not limiting themselves to supply chain and engineering changes, they achieved improvements in product design and development producibility, quality, reporting and data collection, material costs and logistics. As they led the charge for supply chain redesign, they realized a five to one return on their investment in supplier training.

Along the way, they stumbled and sputtered at times, but they always maintained focus, paving a clear path to a continuous improvement journey. They are learning how to become a better competitor, customer, and organization as they continue to improve their processes.

For question or comments relating to the article or lean tools and techniques, please email authors.

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