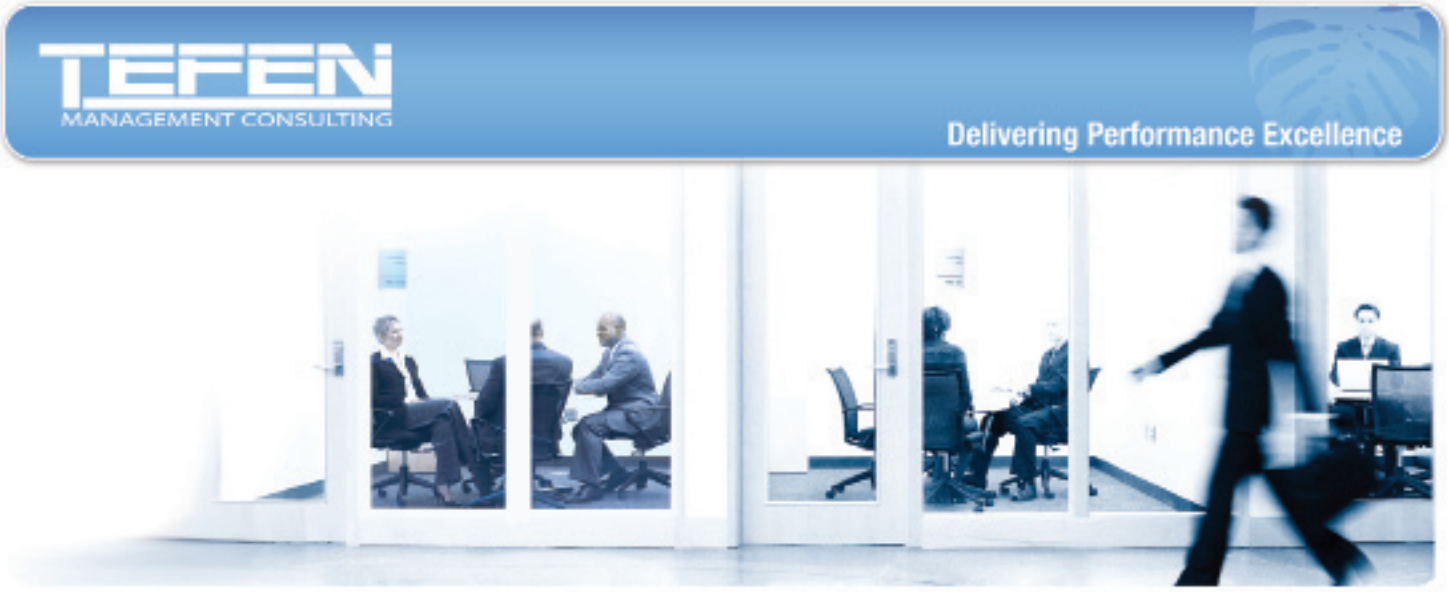

Capacity Improvement in a Pharmaceutical Manufacturing Company

A large pharmaceutical company, specializing in generics and drug delivery was at maximum production capacity. The company's business objective included a target of $30 billion in annual sales. Unable to expand their existing facilities, the client engaged Tefen to increase capacity in their existing operations using lean methodologies.using lean methodologies.

Challenge

The client had 42 different products, requiring 37 different manufacturing processes. After performing the initial diagnostic, Tefen found that the combination of the facilities design, product mix, and different manufacturing processes resulted in a moving bottleneck that restricted manufacturing capacity.

Prior to Tefen's arrival, the client's approach to production capacity was to reallocate labor to compensate for the product mix and moving process bottlenecks. Labor became the measure for capacity. This linear Materials Requirement Planning System (MRPS) could not account for changing production constraints. Management prepared weekly and daily production schedules to allocate people to processes, and when delays occurred, meetings were held to manage production. As a result, products in process were frequently stopped and changed over in an effort to "keep the labor working" and "maximize capacity." As a result of these frequent change-overs, WIP storage, lost materials, and high variability in testing support, a significant increase in customer lead time occurred.

The client was also having difficulty completing product documentation and validation testing on time. Tefen's

diagnostic found a disconnect in communication between the cross-functional departments, resulting in a 12-15 day review cycle to complete batch record documentation. These complexities caused a delay in product shipment, resulting in an annual increase of $600,000 in transportation expediting costs.

How Tefen Helped

Working side by side with the client, Tefen helped improve capacity through the application of lean methodologies to eliminate waste, minimize frequent changes in production and process change-over's, and lower the number of errors.

Key Performance Indicators: Tefen provided the management team with a metric dashboard to define and measure KPIs to track trends in capacity, cycle time, efficiency, and quality on a weekly and monthly basis.

Manufacturing Batch Record Review Process: Tefen redesigned the original process with visual controls and simplified recording tasks to reduce data entry errors and cycle time. In addition, hijunka methods were combined with a document-locator kanban to prioritize work and keep documents from stalling at various hand-off points. If documents exceeded the set limit on each Kanban, a "red-light" response was triggered to correct problems in processing early on to prevent delays.

Equipment & Supplies: A major issue observed in the diagnostic phase was cluttered manufacturing hallways, causing workers to spend time "hunting and gathering" equipment and supplies. Tefen's 5S implementation organized equipment and supplies in designated locations to improve storage and space utilization.

Scheduling: To minimize daily and weekly production changes, Tefen implemented a real-time visual scheduling system based on key constraints in manufacturing to manage production and reduce delays. As the visual production schedule system matured, a significant drop in excess labor and costs was observed.

Manufacturing Throughput: Tefen implemented a materials kanban system to minimize WIP and match material replenishment to demand. Using a kanban pull system, all necessary raw materials were available within 12 hours of production.

Quality Control Lab: Operations were slowed down by long testing time, sensitivity to changes in manufacturing schedule, analyst workload, and long time spent gathering materials for samples and supplies. Tefen

streamlined the lab processes utilizing 5S and other similar visual scheduling systems. This enabled management, organize the testing batches and mange the timing of lab resources.

Manufacturing Change-over and Set-up Time Reduction: Tefen worked with supervisors and operators to develop new processes to reduce the duration and variability of changeovers and equipment set-up. These processes include: Checklists with time goals to avoid duplicated cleaning, Creation of cleaning supply cabinets to save time, Streamlining and coordinating material lot changes, "SMED" implementation, and the identification of opportunities to reduce the verification and frequency of cleaning and setup.

Trouble Shooting: As a "young" company, many important functions were contingent upon one or two key individuals. This contributed to significant delays in production if these individuals were not available for consultation. Tefen empowered operators to do basic troubleshooting by providing them with Troubleshooting Guides for each major piece of equipment. This helped reduce the wait time for the maintenance staff to respond to simple equipment malfunctions.

Continuous Improvement: Tefen defined and implemented a continuous improvement framework consisting of governance, sustainability, and proficiency models to manage the on-going monitoring and improvements of the business.

Performance Excellence Delivered

With Tefen's help the client adopted lean methods and achieved a 25% increase in capacity without expanding their facilities. In addition, Tefen's lean methodologies allowed for additional improvements in the following areas:

Batch Record Review Process: The manufacturing batch record review process cycle time was reduced from 10 days to 3 days resulting in the air-transportation costs to be eliminated. In addition, Tefen was able to reduce the complex batch record format to minimize errors and manage cross-department hand-off.

Manufacturing Throughput: Within the first 3 - 4 weeks of implementation, high levels of WIP were virtually eliminated. In addition, capacity improvements were made in several of the processes by reducing the non-valued-added activities negatively effecting process performance.

Change over time: Following implementation, metrics indicated an immediate and consistent decrease in change over time by 30% from 14 hours to 10 hours.

Quality Control Cycle-time Reduction: Within the first 3 weeks of implementation, the QC testing cycle-time improved from 26 days to 16 days. On average, Quality Assurance review time decreased from 5 days to just 1 day, making the product available to market quicker.

Sustainability: In order to maintain improvements, Tefen created sustainability plans. Tefen worked with the QA group to implement a new schedule for the review of the results conducted by QC.
In addition, visual tools were used to foresee the output of the lab and plan their resources accordingly.
To maintain work place organization, 5S owners were made responsible for each of the shifts, utilizing check-lists. A monthly 5S audit is being conducted for maintenance and on-going sustainability.

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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