Improve Material Flow at Supplier

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Abstract *— This project will be focused in reducing the high lead time that characterizes one of the suppliers in a Medical Device Organization. By reducing the lead time of this supplier, the organization expects to have several positive effects in other areas such as supplier quality performance, product field performance and eventually marketing indicators. Cause and Effect diagrams have shown that the high lead time of this supplier is the main contributor (root cause) for material availability issues in the field (which causes loses in sale). In order to have a methodical system to ensure project is successful, Lean Six Sigma will be used. Literature Review section explains how Lean Six Sigma methodology will be used to develop the project*.

Key Terms *— Analyze, Improve, Measure, Supplier Performance.*

PROBLEM STATEMENT

Back in 2006, a Medical Device company made the decision to outsource 30% of the manufacturing process required to assemble a pacemaker and a defibrillator. The decision to outsource these processes brought various positive contributors to the financial status and even some free space for new products. However, this decision also brought some negative indicators that were impacting the long term goals of moving out of a push system into a pull system (supplier selected was not involve with Lean manufacturing initiatives). Additionally, the field population was complaining of material availability issues due to the high lead times of the product. Main contributor for the high lead time was the cycle time of a supplier.

As part of the continuous improvement plan, it was decided to work on a Supplier Development strategy that could help the organization improve inventory in the field (reports showed several products in allocation due to supplier issues), decrease scrap levels, reduce lead times and move from a push system to a pull system.

Data from all the suppliers was collected and Paretos showed that the supplier chose to outsource the manufacturing process, which is located in Tijuana Mexico, was the top offender in many categories. This supported the initiative to implement Lean Sigma methodology at this supplier. This project describes the methodology used to decrease the overall lead time of this supplier while getting other benefits such as: lower inventory levels, decreased in quality events associated to this supplier (increased in internal detect-ability), additional space (freed through this exercise) which could be used for new transfers and a sustainable and reliable material flow among others.

RESEARCH OBJECTIVE

The problem statement for the project has been defined as: High lead times, and in process quality issues, causes line disruptions (approximately 18/year) and yield issues (baseline yield of ~ 78%) among other problems, at the supplier. These not only affect the production process at the supplier, but eventually translate into high lead times, quality and material availability (shortages) issues at Medical Device High Volume facilities.

The goals and objectives identified were:

- Reduce lead time (from warehouse to final pack) at least 30%: Current lead time is between 10-14 days, depending on model

complexity. The goal is to reduce the overall lead time to 7-8 days in average.

- Improve quality issue detections at the supplier's site (instead of detecting it at the Medical Device organization site) least 30%:Currently this supplier has a lot acceptance of ~80% in the incoming inspection area. Mostly cause because their current kanban system does not allow them to detect in house their quality issues (The inspectors capture them in receiving inspection). The goal is to improve the lot acceptance to 95% in the receiving inspection.
- Free at least 20% of Clean Room space (Space optimization): New products transfer is requiring to free at least 150 sq ft in the clean room. The main purpose is to allow space for new equipment (already order) which will be used as part of the manufacturing process of new products.
- Reduce labor by 25%: By moving from a "batch and queue" to a "one piece flow" process we should be able to better allocate some of the operators into new products of into continuous improvement efforts.

RESEARCH CONTRIBUTION

Throughout this project, it is expected to achieve several objectives in the internal organization, in the supplier's organization and infrastructure and most important in the patients served.

Starting with the contributions in the supplier's organization, it is expected to achieve:

- Overall Lead Time reduction of 30%
- Manufacturing space reduction of 15% (Free space increase by 15%)
- Full deployment of a Lean Sigma methodology with management commitment of moving into a cultural enhancement. (Cultural change requires time, changes in beliefs and most of all management and employee engagement)
- Implementation of Continuous improvement (Kaizen) which can be used to eliminate or reduce all the unnecessary inventory, equipment, and tools from the workplace.
- Implementation of the so called "5S" method or Visual Management which can support/perform the cleanup activities required at the workplace in order to eliminate or reduce *Muda*.
- Implementation of Lean Purchasing, which will help with aspects such as: Ordering Time Reduction, Kanban Control System, Quality at the Source, JIT Delivery, Reduction Number of Suppliers, Long-term Contracts with Suppliers (stability) and Better Relationships with Suppliers (reliability).

Within the Medical Device organization, it is expected to achieve benefits such as:

- Decrease material availability issues in the field: This will help improve the market performance by always having product available when required by customers. Currently the field force has been receiving complaints due to the lack of certain models available. This translates into sales losses. This project will benefit in this area.
- Increase Supplier performance by 10%
  Regulatory agencies have shown concerns with low supplier performance. The receiving area, inspect using AQL/sampling therefore having low supplier performance increases the risk of non conforming material outside the control of the organization. The project will benefit in this area, targeting an increase in supplier performance.
- Improve customer satisfaction rating by 20%: This will improve as a consequence, once the material availability performance and the supplier performance rating improve.

LITERATURE REVIEW

This project will be developed using Lean Six Sigma tools such as the DMAIC methodology (DMAIC stands for Define, Measure, Analyze, Improve and Control). Lean will be used to reduce variation (waste) by scientifically balancing the process to manufacture the product in the scope;

while Six Sigma will be used to reduce variation (defects) by applying scientific analysis to the overall process. The synergy between both will help improve supplier's performance while meeting all other objectives such as lead time reduction.

The overall strategy with this supplier is to help them decrease their lead time while improving their process flow to eventually complete transition to a pull system. The scope of this project is limited to the high runners of the pacemaker manufacturing line which is equivalent to the 80% of the high and low voltage product volume in the field.

The first thing to do is to define what constitute Value in the organization, and then will move to develop a complete value stream map (VSM). Once the VSM is completed will proceed to eliminate from this value stream all the identified waste and more important will rethink specific work practices and tools to eliminate backflows, scrap and stoppages of all sorts. A prioritization matrix will be used to develop a plan on how to address all of the opportunities found through the VSM.

Once these steps are completed, the focus is to make the remaining value-creating steps, flow. Having in mind the product, as the primary focus, rather than the equipment needed to assemble it or the organization required to support production.

This will help creating a lean mindset therefore removing all impediments and ensuring a continuous flow in all the activities needed to design, order, manufactured/assembled and distribute a product or service. In the end, all these initiatives will translate in lead time reduction, more detect-ability at the site and the utmost objective, and improved field performance with less material availability issues [1].

METHODOLOGY

DMAIC will be the methodology that will be used. It is an acronym for the problem solving methodology that powers lean sigma. Each letter stands for a phase of that methodology (see below). Each phase has a list of questions to answer, and deliverables that help answer those questions robustly. Tools are then applied to achieve those deliverables, and selected based upon how much rigor is required to solve the problem at hand. Simple problems require fewer rigors. DMAIC can be applied to think through an issue in minutes, or guide a team to solve a very complex problem over several months.

MEASURE

Measure phase started by developing the Value Stream Map (VSM) for the overall process. The steps in a Value Stream can almost always be classified in one of the following three type of actions: (1) those steps that create value, (2) those that do not create value but are unavoidable with current technologies and production assets (type one Muda) and (3) those steps that can be found to create no value and to be immediately avoidable (type two Muda). The analysis to generate the values stream and classify each step was performed with supplier's employees, Medical Device manufacturer employees and other experts involved in the production of the goods been analyzed.

Categorization helped identify Muda and most important it separated those steps that are required or add value to the end product. Once steps from the VSM were categorized, Data collection Plan was developed to document all potential variables that could have input into the process.

VALUE STREAM MAP

A Value Stream Map was created by a multidisciplinary team that included not only personnel from the Medical Device organization, but also from the supplier's, Global Supply Chain, Design, Engineering and sub tier suppliers among others.

Once the process of outlining all steps required to manufacture the product was completed, the next steps was the categorization of each of these. This helped to identify Muda among those steps that add value. Once the Value Stream Map was completed, and all functions were in agreement with the map,

next step was to group them in order to better identify the waiting time and inventory levels between operations.

Throughout this exercise it was noticed that there were approximately 5 days of waiting time among those 12-14 days of overall lead time.

- Critical Equipment: Performance vs. Designed Cycle Time: Will help understand where losses are coming from.
- Understand schedule attainment: Demand vs. shipping performance and Contributors associated to schedule attainment.
- Validate EPEX, schedule accordingly: Every part every interval.
- Dedicate item #'s to specific equipments, schedule accordingly: Review machine work content and dedicate low, med, high if possible.
- Evaluate change-over
- Evaluate how to implement Level Schedule
- MSD (Manufacturing System Design)
- Standardized Work: Balancing, Opt Flow and Layout.
- Validation of critical equipments: Strategically validate more items across equipments.

Additionally, a Spaghetti diagram was developed to understand the travel distance of the operators during the manufacturing process of the product in the scope. Each family was assigned a color to differentiate between processes. It was an eye-opener exercise, revealing there were manufacturing stations required for a single product, all over the clean room.

Additionally, the current layout of equipment and stations was evaluated in order to analyze critical equipments locations, common station location and process flow (per product family). This analysis supported the objective of these activities.

CURRENT LEAD TIME

Data from the last 3 months was taken to determine the average lead time for this supplier. It was noticed to fluctuate between 13-16 days with an average of 14.52 days.

A Process map of critical processes was developed to better understand equipments, processes, efficiencies and input/out variables.

This process map also helped to gather more information about the equipments and processes to ensure this insight was considered in the efficiency analysis, during the equipment location and most important while determining best process flow for this scenario.

ANALYZE

This phase focuses in identifying, prove and sustain (with data) all the major contributors to the Overall Lead Time.

In order to ensure data is driving the results, several tools were used to determine the most critical contributors to the process lead time. Prioritization Tool, Sequence of events, Cause and Effect diagram and SIPOC were the most useful.

The Cause and Effect diagram helped outlined the most important variables, which will be the focus throughout this project.

Once the variables were identified throughout the Cause and Effect diagram a Prioritization matrix was used to prioritize all variables to determine the order in which the inputs will be evaluated and improved. It also helped ruled out those entire variables that do not have direct correlation to the process output.

Waste identified through Value Stream Map and Measure phase. For example: Excessive inventory, Travel time, Non Value Added Work, Non value added inspections, Non standardized workflow, Non standardized work practices, No 5S practices and Push System.

IMPROVE

Key items needed to achieve goals were:

- Card Kanban system in those identified operations: Line balancing process highlighted operations were kanbans are required. Additionally, it also identified areas were

missing signals were causing the process to brake. Card kanban system will be implemented in those areas to ensure input and output signals are clear and visible to all involved.

- Fix inventory levels: Using the historic and future demand, the Global Supply Chain group will help develop the inventory levels required to support the field requirements. Fixed inventory levels will help stabilize the supply chain, and even the overall process.
- Implement Kanbans: Kanbans were implemented in certain operations which will help the process flow of material. Execution of Kanbans will be monitor against plan.
- Determine Takt time: Introducing Takt Time to the organization will synchronize the rate of production to the rate of sales. This technique will be adjusted constantly to help reduce considerably the surges at the end of each financial period ("end-of-the-month syndrome). It is very important to define takt time at a given point in time in relation to demand and to run the whole production sequence to the defined takt time. A key to the success of takt time is to communicate how we are doing against the defined takt time. Raising this awareness will let employees know that the connection between sales and production is very tight. Additionally, the organization needs to take the concepts of Just-in-Time and level scheduling to learn how to pull value through their systems in order to become capable of responding practically instantly to customer orders.
- Complete line balancing: Line balancing will be implemented across all manufacturing lines. The main purpose is to have a Just in time operation with the correct pulse/heartbeat along.
- Reduce WIP: Balancing lines will immediately impact Work in progress (WIP). One piece flow will reduced the risk of quality issues impacting large batches of material.
- Reduce travel: Layout of equipment will be improved in order to reduce travel time of operator. Will develop a layout in cells, where a product can go from start to finish within that area. Avoiding products all over the clean room with higher potential of issues such as material of different lots put together and loosing trace-ability, etc.
- Implement standardized work and workflow: The standardized work and workflow will help ensure things are done the same way all the time. The operators will be involved to ensure instructions are understandable.
- Implement pull system: In the end the overall system will be moved from push to pull. Signals will come from the customer and nothing will move or start until signal is received. Level scheduling is important to the success of this system. Global Supply chain is leading the development of a level scheduling with this supplier.
- Maximize efficiency: Critical items and processes are been evaluated by engineering to determine and implement activities that will improve the efficiency of the overall process. Downtime, Equipment utilization and other contributors are been addressed to ensure efficiency increases.

An Improved Value Stream Map was developed. The improved Value Stream Map shows the impact in waiting time, which was decreased by 40%. The times included in this VSM were data taken after improvements were implemented (approximately 5 weeks of time studies).

Lines were re-balanced using the Takt time calculated. Each configuration or product family had configuration of operations identified and grouped (or separated) to ensure Takt Time was met.

Results of the line balancing exercise were successful. Graphs were developed to show how each operation is meeting the Takt time. This data was collected throughout time studies performed by the industrial engineers, the last coupe of weeks.

Additionally, after completing the re-layout, visual management and process flow implementation, the improvements were noticeable to the eye of the audience. A group of Lean Six Sigma experts: Master Black Belts and Black Belts were selected to evaluate the end result of the project. Their assessment was very satisfactory. Since Lean Six Sigma was implemented in this supplier, the Medical Device organization decided to use this supplier as an example to others.

CONTROL

All standard operating procedures were updated to show the new process flow. All employees were trained and certified in operations. Visual Management (5S) was implemented to ensure easy follow through and monitoring. Process maps detail manufacturing steps, material flow and important variables were updated, and are available for use.

Key product variables identified with importance to customer, desired target value and specification range were defined and documented. Long and short term capability trend charts tracking variation reduction progress are available and updated weekly. Key and critical input variables identified with targets, statistically determined control limits and control strategies were defined and documented. A Reaction plan was put in place for out-of-spec material. Measurement systems are capable with calibration requirements specified. Measurement System analysis were documented showing evidence of capability. Sampling, inspection and testing plans include how often, where and to whom results reported. Operating procedures identify actions, responsibilities, maintenance schedules and product segregation requirements. Training materials describe all aspects of process operation and responsibilities. Process improvement efforts were fully documented and are available for reference. Control plan is reviewed and updated periodically and resides in the operating area.

RESULTS

Once all activities were completed and implemented, data was collected to understand if the objectives of the project were met. Lead time of the overall process was 10-14 days. Lead times after all improvements were implemented decrease to 6.8 days. (Goal 7-8 days in average). Supplier performance at the organization was ~80% (most of the quality issues were not detected at the supplier; instead these were detected in the receiving inspection process). As of January 2011, current supplier performance is 97% (Goal 95% acceptance).

Clean Room space in use by manufacturing process was reduced by approximately 500 square feet. (Goal: 150 square feet). Average head count for manufacturing process was 16 operators. The improved process requires 12 operators. This is a reduction of 25% (Goal: 25% reduction). Note: The four operators will be used as part of the new product introduction process

Additional to all these benefits, all this work resulted into savings for the company. Throughout the reduction of their internal scrap, and improving their yield and efficiency, the supplier agreed in to a price reduction. The price reduction is equivalent to $380,911 per year.

CONCLUSION

The use of Lean Six Sigma methodology in this project was a great contributor to the success achieved. Throughout the methodology focus was maintained and correct tools were used. The value stream map was crucial to identify all process steps and Muda. Team was able to focus in eliminating those steps that did not add value, while implementing flow on those that were required to the product in scope.

Lead time was reduced by ~40%, supplier performance was improved to 97% which is a key regulatory element to a Medical Device organization. Additionally, throughout capacity analysis and equipment utilization, 500 square feet were freed for new products. In the field it was

noticeable the improvement in the supply chain, with zero material availability issues in the past months.

In summary, the project met all the expected benefits identified by the champion and the team. It was proven that the use of Lean Six Sigma was important to the success of this project.

REFERENCES

[1] Williams, M, A, et al, "Overview of DMAIC", *Six Sigma Pocket Guide*, Ninth Printing, June 2002, pp. 5