Surgical Technologies Clean Room Lines Capacity Improvement

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Abstract *— In today's competitive market, medical device manufacturing companies need to continuously innovate their products and process in order to maintain a leader position on the medical devices industry. Quality and Cost will always be two key elements in every medical devices company and driving them through excellence will assure any company a leader position in the market. Due to an increase in customer demand, companies are facing challenges in increasing their volume without increasing infrastructure or operational cost. Lean Manufacturing and Six Sigma projects combine and offer a variety of improvement possibilities to the manufacturing companies. Following a standardize methodology such as DMAIC, projects can be performed in order to improve capacity and productivity and supply required customer demand without compromising product integrity and quality. By using this methodology and Lean Six Sigma guides and tools companies are able to identify sources of muda, analyzing root causes and presenting improvement ideas for a continuous improvement culture.*

Key Terms *— DMAIC, Lean Six Sigma, Quality, Units per Labor Hour.*

INTRODUCTION

For every worldwide manufacturing company the imperatives of Quality and Cost play an important role in each corporate and manufacturing decision. With today's science advance in high efficiency technologies, equipment's and process reliability increase and massive production in low cost countries remaining as leader in the medical device industry is a daily challenge for every medical device company. Innovation is a key element in order to maintain a leader position in a competitive world, not only by developing new products but a also by bringing new and innovated ideas to current processes. Companies are directing their effort to increasing their Quality and lowering their Cost by developing process, equipment and projects focusing in reducing non value added activities and wastes of current product process flow. By the use of the Lean Six Sigma and DMAIC methodologies companies are identifying their areas of opportunities and addressing them using tools like root cause analysis and process controls to sustain changes and establishing a continuous improvement culture among company management and operations in order to keep innovating, increasing quality and reducing unnecessary cost to product and process.

Project Description

A medical device company is currently processing 100% of their surgical technologies product demand through clean room area. The surgical technologies clean room lines processes all their part numbers in a large batch, with process steps in silos resulting in area overall productivity metric in 39 Units Per Labor Hour. Having the outcome in disconnected steps, overtime is needed in order to meet customer demand. The current process yield is of 84% due to excessive rework in all the process steps. Although continuous improvement desire is perceived among team members no standardized methodology has been apply to understand issues root causes and applied effective controls.

Project Objectives

Conduct a Lean Six Sigma transformation at the Surgical Technologies Clean Room area to improve productivity and increase daily output using the Units per Labor Hour indicator, due to an increase in customer demand. Also reduce product lead time throughout the value stream clean room

process and minimize wastes and cycle time of the current process. However the most important project objective is to create a cultural change of continuous improvement among operations team members and operations management team enhancing the importance of process and product quality and proving the tools for sustaining a continuous improvement culture.

Project Contributions

The lean six sigma transformation project will contribute to increase surgical technologies clean room productivity, adding capacity to increase product volume and new products development. As part of the lean initiative current process waste will be minimized and product lead time will be reduced. As part of the six sigma initiative a significant improvement in product quality will be noticeable due to identification of potential causes of process rework and reduction of reprocessing and product rework.

LITERATURE REVIEW

The origin of lean manufacturing in the United States can be linked to Henry Ford (the assembly line), Fredrick Taylor (industrial engineering), and Dr. Deming (father of quality management). In Japan, these concepts were refined and honed by Taiichi Ohno, Eliji Toyoda, and Shingeo Shingo to create what is now known as the Toyota Production System (TPS).

Ohno identified seven types of waste. There are several ways to describe these "7 deadly types of waste" that occur in a system. The most common are:

- Overproduction – producing more than the customer has ordered. Many times producing to forecast or batching to save setups can lead to over-producing.
- Waiting – time when no value is being added to the product or service. High levels of inventory, people, parts, or information can lead to long non-value added waiting.
- Transportation – the unnecessary movement of parts, moving multiple times, movement that does not add value. High levels of inventory, the layout of the system, and priority shifting are just a few things that can also lead to non-value added transportation.
- Inventory – unnecessary raw material, work-in-process (WIP) or finished goods. "Stuff" we have made an investment in that the customer doesn't currently need. Long cycle times, "just in case" thinking, and flow issues can also add to inventory issues.
- Motion – unnecessary movement of people that does not add value. Poor workplace organization and workplace design can lead to waste in motion. These motions at times can lead to serious health and safety issues.
- Over processing – adding steps or processes that do not add value to the customer, thinking that continuing to work on something makes it a higher quality part or service. This is considered waste when the customer doesn't require that "extra" touch.
- Defects – work that requires rework or, even worse, work effort that needs to be scrapped. Bad processes, equipment issues, and lack of in-process control can add to the defect problem. Obviously, the more "stuff" in the system, the higher the percentage of defects.

Logically it can be seen how over-producing can lead to contributing to all the other waste. All wastes can be associated with any environment, not just production. Understanding and identifying waste in the system can help target improvement efforts. [1]

When companies speak about performing projects for increasing productivity, capacity or performance its important to understand that the improvements will not sustain if the team performing them is not adequately trained or understand the reason and purpose for the improvement. The Lean Manufacturing System is both a technical and a social system. It requires leaders who are capable in both areas able to use

tools expertly and to engage and develop people in order to make continuous improvement a daily reality. With an effective leader as a teacher and a daily coach, process improvement and people development go hand in hand [2]. The founder of Daoism Lao-Tsu once said “Go to the people. Live with them. Learn from them. Start with what they know. Build with what they have. But with the best leaders, when the work is done, the task accomplished, the people will say "We have done this ourselves."

There are at least five reasons that make it worthwhile to consciously create and sustain a healthy culture. First, goal alignment is much easier. Second, workers are more highly motivated in a predictable culture and will not only take action with more confidence; they will also be more likely to initiate new methods. Third, a culture can provide some needed structure and avoid the bureaucracy that dampens enthusiasm, innovation, and actions in general. Fourth, until the changes made as part of the lean transformation become part of your culture, the gains will be not be sustained over time. Your lean transformation will lack "stick ability." Fifth, even if you make no conscious effort to create a culture, one will "occur" spontaneously. This organic culture may either help or hurt your business. However, it is much better to intentionally design and create the culture you need, rather than having it develop organically as a result of the lean transformation. [3]

When implementing a lean six sigma project is important to understand the objective of this process which is not just a performance improvement effort but a product quality and value, customer perspective and cultural improvement change. The following elements define what Lean Manufacturing focus about.

- Specify value – As stated by Womack and Jones, “The critical starting point for lean thinking is value. Value can only be defined by the ultimate customer and it’s only meaningful when expressed in terms of a specific product (a good or a service, and often both at once), which meets the customer’s needs at a specific price at a specific time.” Value Stream Mapping is a process to detail and analyze the flow of material and information to bring a product or service to the customer. After identifying the entire value stream for each product, we can separate actions into value added (VA) and non-value added (NVA) activities. Value Added activities can be defined as something that the customer would be willing to pay for; an activity that changes the form, fit, or function of the product or service and is done correctly the first time. Non-value Added is something that takes time, resources, or space and does not add value to the product, and thus adds no value to the customer. Identifying the value stream will expose many NVA activities.
- Create smooth flow – When the value-creating steps are understood, the next step is to create continuous flow. Things like producing in small lots versus batching, putting machines in the order of the processes, pacing production to Takt time, and the application of lean tools all create smooth flow. Creating smooth flow can dramatically reduce lead time and waste.
- Customer pulls value – Once the first three principles are in place, we can now put a system in place that only produces at the rate of customer requirements, a “pull” system. This is the opposite of “push,” releasing work into the system based on a forecast or a schedule. No one upstream will produce a good or a service until the customer downstream is ready for it. Pursue perfection- Lean says we must continually understand value through the eyes of our customer and refine our value streams to increase the flow based on customer demands. We want to move toward perfection. The process of improvement never ends. [1]

METHODOLOGY

Most of the worldwide manufacturing companies had followed and adopted the Toyota Production System in order to maintain a leader

position in the manufacturing industry. Toyota Production System has evolve across the years to become Lean Manufacturing and combine with Motorola's Six Sigma methodology, now days most companies use the Lean Six Sigma methodology to drive improvement initiative at their workplaces. Using this systematic and standardize methodology approach a multifunctional team will work together to achieve the project goals. Project purpose is to improve process productivity, increasing capacity due to customer demand and reducing non-value added activities and waste from current process, additional to increasing process yield by reducing rework and reprocessing. Therefore the Lean Six Sigma methodology was selected to drive a Lean Transformation combine with Six Sigma DMAIC methodology to improve area performance and quality. Following DMAIC the project will be divided into five phases (Figure 1). Each phase will be reviewed in a tollgate with Master Black Belts, to receive feedback and guidance before continuing to the next phase.

Figure 1
DMAIC Process Steps

Define Phase

The first step of DMAIC methodology is called the define phase. During this phase the problem statement is describe and the project scope is establish, as well as project goals and project Y. On the define phase an agreement with the customer is reach on what is the problem or the pain that is causing to the business and what are the expectations of the project. An important part is to define project timeline, with project start date, end date and when the expected benefits would be seen. Once the problem statement is created, and the project goal and timeline are stated an analysis about the team members and stakeholder is performed. The customer and the project leader define what would be the project core team and the allocated time they will have for the project. Some of the documents that will be used for define phase will be the project charter and stakeholder analysis.

- **Project Charter** – Defines the problem statement scope, project goal and expected completion date. In the project charter the team members and stakeholders are define and their allocated time for the project. This document is considered a commitment between the project sponsor, project leader and team members.
- **Stakeholder Analysis** – The stakeholder analysis is use to understand the objectives, expectations and concerns, if any, of the stakeholders and project team.

Measure Phase

During the measure phase the baseline data of the project is gathered to understand the current state of project scope. By evaluating quality, lead time and process data a better understanding present situation can be comprehended by the project team. In measure phase there is no intention of providing a possible solution for the problem or present possible improvements, however by collecting relevant data and learning to see and identify wastes and inefficiencies in current process there will definitely be a clear focus on which problems the team should emphasize to drive improvements that will impact substantially the project benefits. Some of the tools that will be uses during measure phase are time study analysis, value stream mapping, defect Pareto and performance charts.

Analyze Phase

After measure data is collected and baseline of current state is defined the project team begins to analyze the collected data. This process is part of the Analyze phase were its purpose is to identified the possible root cause which affects the process and contributes to current state situation. The team

needs to evaluate the data that was collected by the time studies analysis and performance graphs to identify what types of muda are in the process and what are the possible offenders that contribute to the process performance. After analyzing, identifying and prioritizing which causes are the major offenders to the process the team will begin to think of what improvement initiative can be leverage or created to improve

Improve Phase

After analyzing, identifying and prioritizing which causes are the major offenders to the process the team will begin to think of what improvement initiative can be leverage and created to improve process and attack the issues from their root cause. During the Improve Phase the changes to the process will be performed and the potential solutions will be documented and implemented.

Control Phase

The last phase of the DMAIC methodology is the Control phase, which its purpose is to establish appropriate controls to the implemented improvements in order to sustain them and achieve a level of maturity in the new established process. The control mechanisms established in this phase will help prevent the recurrence of the issues that affected the baseline state and if any new problem is detected the team will have the tools to addressed them using a standardize methodology.

RESULTS AND DISCUSSION

The results obtained during the project are discussed in this section following the systematic approach of DMAIC. During project execution, the progress of each phase was presented on a tollgate with master black belts and stakeholders

Define Phase

A first team meeting was performed with the project leader, sponsor and the team members during the define phase. Meeting had the purpose of developing a project charter and discusses the current situation of the area, the scope and the goal of the project. After redacting the project charter (Figure 2) the team defined their allocated time and role in the project as well as a stakeholder analysis (Figure 3) to understand their expectation. A communication plan (Figure 4) was redacted by all the team members and sponsor to define which meetings will be held and its frequency. This document help the team manage an effective agenda and communication. Another document that was created was the risk assessment (Figure 5). In this document the team identifies potential risk that can affect project completion or performance. These risks are classified as threat or opportunity and a backup plan is defined for each of the risk. Additional to the project charter a SIPOC diagram, described in Figure 6, was created to understand current process and its inputs and outputs. This type of diagram helps the team to clarify any doubts on the scope and defines a clear vision on what elements to focus.

Project Charter	
PROJECT NAME	Productivity Improvement ST CEA
LSS COACH	Master Black Belts
PROJECT LEADER	G.Cruz
PROJECT SPONSOR	Manufacturing Manager
PROJECT DESCRIPTION	Improve ST Clean Room Capacity due to increase in demand
PROJECT STATEMENT	Currently 100% of ST demand is process through clean room area. ST clean room processes all part numbers in large batch, with process steps in functional silos resulting in area overall UPLH of 39. Having the outcome in disconnected steps with overtime needed to meet customer demand
BUSINESS CASE	By improving the area UPLH, we will be able to improve Clean Room capacity , reducing over time, workforce and meet succesfully
PROJECT SCOPE	ST Clean Room process
NOT IN SCOPE	ST secondary operations and boxing

HARD DOLLAR	SOFT DOLLAR	BENEFIT	TARGET
$101,816	$40,726	$142,542	$70,000.00

Figure 2
Project Charter

Productivity Improvement ST CEA Stakeholder Analysis			
Role	How this change will affect the stakeholder	Main expectations of stakeholder from project	Planned actions/key messages
Lean Six Sigma	LSS Knowledge	Provide Lean Six Sigma tools and the project management	Project Management
Mfg. Engineer	Manufacturing procedures and process configurations	Engineering support at manufacturing practices and configurations	Manufacturing Changes
Supervisor	Daily Production	Provide potential ideas for process improvement and feedback in evaluation process	Process changes
Supervisor	Daily Production	Provide potential ideas for process improvement and feedback in evaluation process	Process changes
QA Engineer	Quality Issues, Yield performance	Provide potential ideas for process quality improvement and rework reduction	Quality Related Changes
QA Engineer	Quality Issues, Yield performance	Provide potential ideas for process quality improvement and rework reduction	Quality Related Changes
LSS Engineering Intern	LSS Knowledge	Support data gathering and support with Lean Six Sigma tools	LSS support

Figure 3
Stakeholder Analysis

ST Clean Room Capacity Improvement Communication Plan						
Target Audience	Communication	Objective	Key Message	Channel	Responsibility	Frequency Date
Leadership Team	Project Initiation and support	Go/NoGo	Justification to move forward with project	Presentation	OE Lead, Project Leader and Sponsor	One for each
Team Member and Stakeholders	Kickoff meeting	Startup and engament	Project Roadmap and Life Cycle	Meeting	Project Sponsor and Project Leader	At project startup
Sponsor	Status Report	Bi-weekly update	Status, issues, risks, review, next step	Presentation	Mfg Ops Staff, OE Lead, Project Leader	Bi-Weekly
Team Members	Status Report	Weekly participation	Status, issues, risks, review, next step	Status Meeting	OE Lead and Project Leader	2 times per week
Project Leader	Status Report	Weekly participation	Status, issues, risks, review, next step	One on One	OE Lead	Weekly
Key Stakeholder from other areas	Status Report	Update	Status, issues, risks, review, next step	e-mail or conference call	Project Leader, OE Lead	Bi-Weekly

Figure 4
Communication Plan

ST Clean Room Capacity Improvement Risk Analysis				
No.	Potential Event or Scenario	Risk Description	Threat or Opportunity	Risk Mitigation Action
1	Resources Availability	Loosing team members during project due to business needs	Threat	Dedicate resources backup to project in case of primary resource absent
2	Lack of employee engament/ownership	Personnel not supportive to project initiatives due time availability or discrepancy in proposed ideas	Threat	Weekly Progress update and feedbacks meetings to evaluated all ideas and decide which are going to be implemented
3	System/Software limitations	Current softwares or manufacturing systems can not operated with proposed ideas	Opportunity	IT involvement in case of system or software changes needed
4	New equipments, workbenches or purcharses Backlog	Purcharses not received at expected date, consequently delaying project implementation	Opportunity	Evaluate differrent local supplier and expedite orders
5	Unavailabity of project goal	Not received project expected benefits after implementation	Opportunity	Re-evalute project analysis and design. Propose project revamp or phase 2

Figure 5
Risk Analysis

S	I	P	O	C
Cleaning	Stem Pouch	Label Printing	Label at Pouch Stem	Assembly
Label Printing	Label at Pouch Stem Tubes & Caps	Assembly	Assembled Unit Label at Pouch	Sealing
Assembly	Assembled Unit Label at pouch	Sealing	Completed Unit	Final Inspection
Sealing	Completed Unit	Final Inspection	Completed Unit	Packaging

Figure 6
SIPOC Diagram

Measure Phase

For defining the current state in the measure phase a data collection plan was established based on the KPI that will measure project performance. The four KPIs that were stablished are Manufacturing Space, Cycle Time, Units per Labor Hour and Lead Time. For the manufacturing space, current surgical technologies base area has 803ft² that are divided in 3 manufacturing line, which can be appreciated in Figure 7.

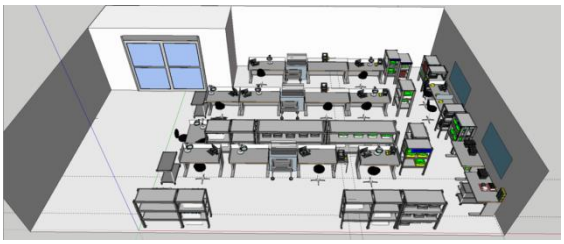


Figure 7
Surgical Technologies Clean Room Area

For understanding the current process, video measurements were gathered of the four process steps that were included in scope. Three different operators were video tape performing current process. After the videos were taken the team meet with the operators to analyze the videos that were recorded and divide the process steps in cyclical work and periodic work. For the UPLH metric, six months historic data was gather by the supervisors and divided per month and shift to define baseline productivity of the area. As well as the UPLH lead time data was based on 6 months historic data. Additionally to gathering productivity data, information about quality performance was obtained. Current process has a FRY percentage of 84% due to high amount of rework in all the steps. In order to analyze in the next phase which could be the possible causes of the high amount of rework a product flow diagram was develop as shown in the Figure 8 and the diagram summary can be found on Table 1.

Table 1
Handling Flow Summary

Journey	Counted	Inspection	Handling	Total
Stems	**2**	**2**	**7**	**11**
Labels	**1**	**1**	**2**	**4**
Pouches	**3**	**2**	**7**	**12**
Tubes	**1**	**1**	**2**	**4**
Caps	**1**	**1**	**2**	**4**
Assemble	**3**	**3**	**8**	**14**
Lot bin			**8**	**8**
Total Handling =				**57**

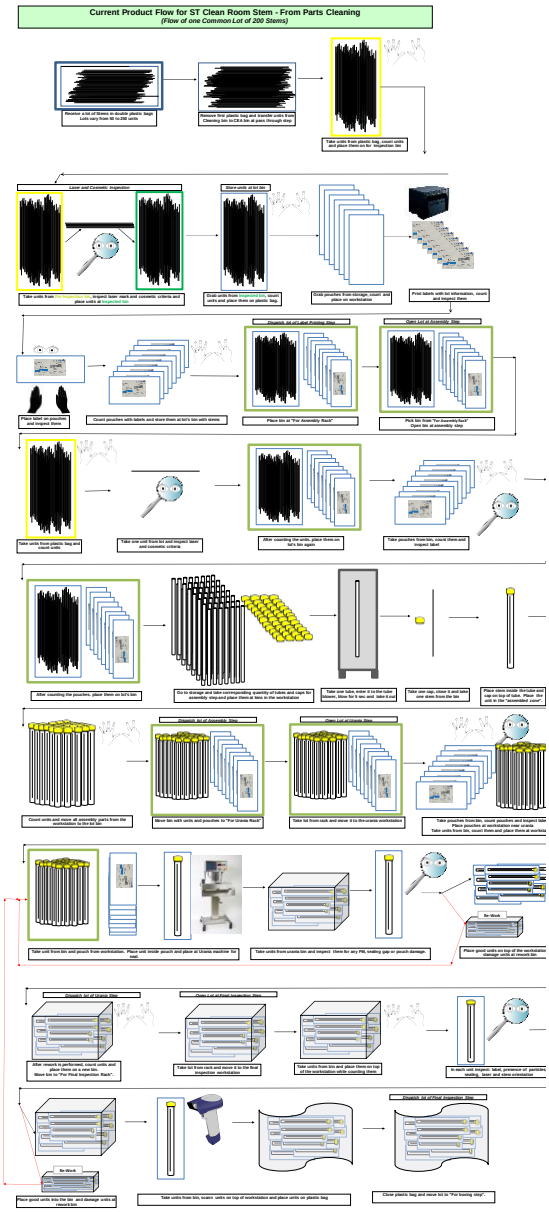


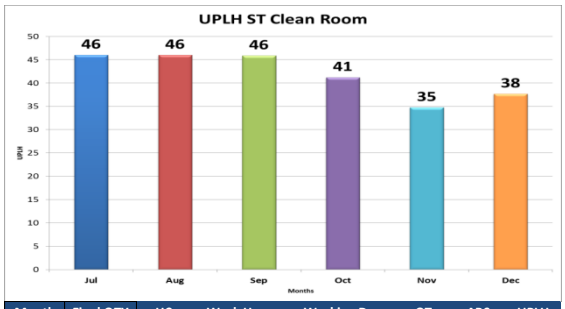
Figure 8
Handling Flow Diagram

In addition of performing the handling flow diagram information of lead time using a time frame of six month historic data was prepared to understand current process lead time. With this information a value stem map was defined with improvement opportunities. Average lead time of one lot for the selected four steps is 2 days.

With information gather about manufactured units, team members that worked in the area, over time and absenteeism per month the team calculated the Unit per Labor Hour per month. In Figure 9 detail information and graph are presented.

$$UPLH = \frac{Units\ Manufactured}{Worked\ Hours}$$

$$Worked\ Hours = Team\ Members * Working\ Hours + Overtime\ Hours - Absenteeism\ Hours$$



Month	Final QTY	HC	Work Hours	Working Days	OT	ABS	UPLH
Jul	115634	14	8	21	279	118	46
Aug	110257	13	8	21	370	157	46
Sep	105367	12	8	21	506	225	46
Oct	108657	13	8	23	394	150	41
Nov	110257	19	8	18	680	245	35
Dec	103587	19	8	17	260	95	38

Figure 9
Six Months Units per Labor Hour Data

Analyze Phase

After gathering all the required information for a better understanding of the current situation, all the measure data was analyzed in order to identify possible causes of current issues and improvement opportunities. Based on the selected KPIs the first analyze data was the cycle time measurements that were collected using video tape analysis. After analyzing all the videos from the four selected process steps and dividing the time into cyclical work and periodic work the team stratified the data into value added work and non-value added work. From the analysis one lot of 200 units could take 13,162 seconds to be processed in the four steps, not taking in consideration possible waiting time due to high wip or abnormal situation. From the 13,162 seconds which represents the process time, 5,240 seconds are from value added activities and 7,992 seconds are non-value added activities. In Figure 10 a Pareto chart is shown with the classification of the work content.

For analyzing the quality data that was documented in the measure phase a brainstorming and kaizen activity was performed with the quality engineers, operations team and line operators in order to identify what types of risks could be found

in the process that could represent a threat for the product integrity, process quality or compliance issue, this assessment is called First Time Quality. Baseline data of RTY (Rolled Throughput Yield) was used and opportunities found in the time studies for mapping the current process identifying risk, classifying them in order of impact and occurrence and finally prioritizing them, based on their classifications. After the priority list was developed the team begins a kaizen to define and design which controls would be implemented to eliminate the potential risk of the process.

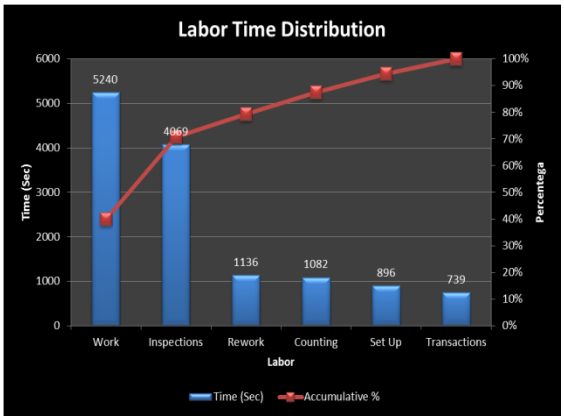


Figure 10
Labor Time Distribution

After the First Time Quality activity was performed and the work content information was stratified into value added and non-value added work the team begins to develop possible designs for improving the area productivity and capacity. One of the non-value added activities that the team found in every step was that each step had two transactions, one at the beginning when the lot was received and one at the end when the lot was going to be dispatched for the next step. Also at each step the operators had to count when they receive the lot and prior to dispatching the lot to assure no unit was lost while processing the lot. In the brainstorming ideas, the operators redesign the process into one process step containing the four activities that in the base condition were separated and performed by different operators. In Figure 11 some of the brainstorming designs are shown.

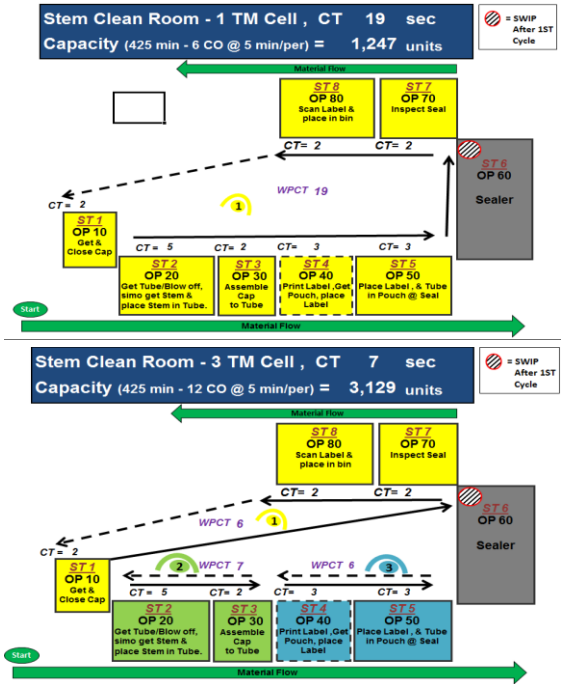


Figure 11
Process Flow Brainstorming Designs

Improve Phase

For the Improve phase the team begins to work with the identified improvement opportunities and brainstorming designs for a new process flow. The base condition manufacturing space had three manufacturing lines that occupied 803ft², however with the proposed cell design manufacturing space was reduced to 564ft² by connecting the four process steps into one cell step worked by two operators. In Figure 12 final cell design is presented.

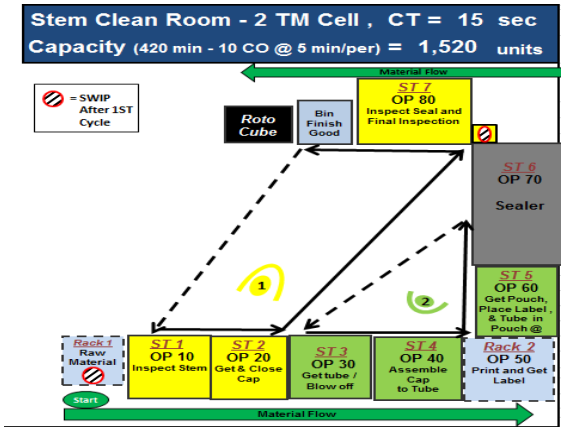


Figure 12
Cell Process Design

Another improvement that was implemented was the use of a close fixture in order to reduce raw material exposure to any forging material that could be in the area. Additional handling flow was reduced from 57 touches to only 20 touches which made a very significant difference in the rework number per lot, since handling touch was identified to be one of the major offenders for the rework per lot. In Figure 13 and Table 2 a detail explanation of new handling flow is presented. Also inside the cell area the team members work one piece at a time which gave them a better inspection and quality rather than working with 200 units at a time.

Table 2
Summary of Cell Handling Flow

Journey	Counted	Inspection	handling	Total
Stems	0	1	2	3
Labels	0	1	1	2
Pouches	0	0	3	3
Tubes	0	0	5	5
Caps	0	0	1	1
Assemble	1	1	2	4
Lot bin			2	2
Total Handling =				20

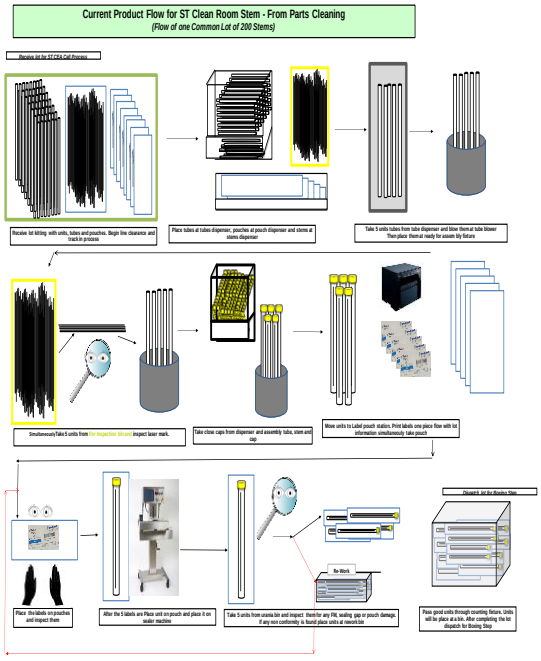


Figure 13
Cell Handling Flow

In order to keep track of day to day production and document if any issue was encounter in the process each cell has a production board where supervisor assign the corresponding lots to each cell and the team members document their start time, end time, downtime if any and the reason of it and if they had any rework or scrap. In Figure 14 an example of the electronic production board is presented.

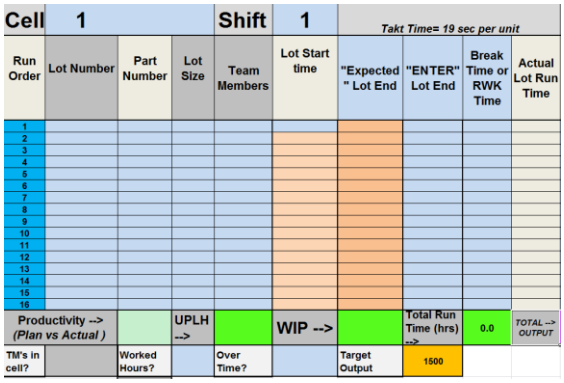


Figure 14
Electronic Production Board

Control Phase

In order to assure the sustainability of the implemented changes controls were established and daily monitored. Some of the controls that assure the compliance and quality of the product and the process are Standard Procedure Operating Document (SPOD) which detail process for the new equipment and process. Also Standardize Work Documents were created as a guide to the team members on the movement sequence inside the cell and product flow. As part of the implemented controls one rotating board, also known as Rotocubes were assigned to each cell. In this Rotocubes Performance KPIs such as Productivity, WIP, Lead Time and Output are place and filled by the cells team leader at the end of each shift. Each month a performance summary is developed with the information gather during that month. Additional to KPIs, 5S audit and daily Kamishibai are performed on a daily basis by support team, quality, operations and organizational excellence. On Figure 15 an example of a Rotocube and KPIs are presented.

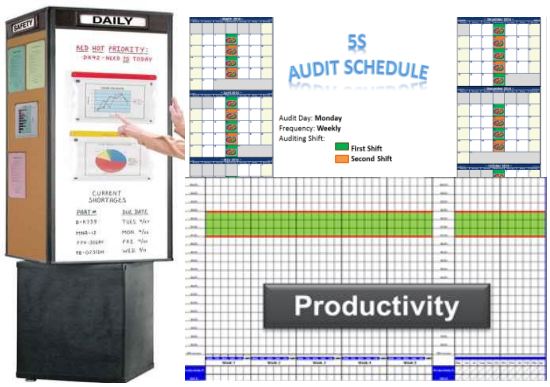


Figure 15
Cell Process Design

CONCLUSION

The surgical technologies capacity improvement project using Lean Manufacturing with a DMAIC methodology approach return the expected benefits that were projected during the define phase. Following the guidance and advices of Master Black Belts and analyzing the collected data during the measure phase the team was able to identified sources of muda on the baseline process and improvement opportunities. Using kaizens, brainstorming and quality initiatives the team could identified root causes of the major issues and by analyzing them proposed possible solutions that in the improvement phase were implemented and successfully controlled using KPIs and sustainability controls. All improvements targets based on project KPIs were successfully exceeded and are detail on the Table 3. However the most important achievement on this project is the cultural change that was accomplished by the manufacturing team members. They were trained in Lean Six Sigma and DMAIC methodology, certified as Yellow Belts and they dedicate weekly one and a half hour to problem solving, that is when they stop production and meet with manufacturing engineers, quality engineers and organizational excellence engineers to solve their problem using a DMAIC methodology approach. This is certainly the most important achievement because it assures that the continuous improvement culture has been implemented and the implemented improvements will sustain and continuously improve over time.

Table 3
Cell Process Design

KPI	Base	Target	Actual	% Improvement
UPLH	42	60	82	**49%**
Cycle Time	218 min	90 min	70min	**67%**
Lead Time	1.37 days	1 day	.7 day	**27%**
RTY	88%	92%	94%	**6%**
Team Members	19 TM	14 TM	Cell TM= 11	**42%**

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