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Abstract — In this project we will see the application of SMED (Single Minute Exchange Dye) a Lean Manufacturing tool in the Medical Device Industry, and how it helps to reduce the time of changeover in a machine. One of the benefits of this tool is to help manufacturing to increase the OEE (Overall Equipment Effectiveness) of the machine thru the increase in utilization.

Key Terms — *Changeover, DMAIC, Lean Manufacturing, SMED.*

RESEARCH DESCRIPTION

This research will bring a comprehensive study of one of the lean manufacturing tools, SMED. It will allow a better understanding of the SMED process, what steps are necessary and how they contribute to the overall time reduction of the changeover process.

RESEARCH OBJECTIVES

The research objective is the reduction in time by 50% for the changeover process of the Tic's machine using SMED. Create a standardized worksheet and a checklist. Have a tool kit for machine parts used in the changeover. Standardize the tools they use and provide them with a toolbox with the ones they need.

RESEARCH CONTRIBUTIONS

This paper will contribute to the application of this method in the medical device industry. How it was applied and the steps required for the implementation of this method. The application of this method will lead to a better OEE of the machine.

The typical benefits from this application include better performance, increase in availability

and better quality of the machine. Ultimately all these benefits leads to a substantial economic benefit to the manufacturer.

RESEARCH BACKGROUND

The Tic#1 is the first couple of machines that had new technology for insert molding an anesthesia needle. The anesthesia needle is made of two components, the cannula and the stylet. The TIC#1 is composed of two separate insert molding machines. One molds the cannula and the second molds the stylet. The insert molding process takes the cannula or stylet and mold the hub or handle around the piece of metal.

The goal of any manufacturer or service provider is to increase profits giving the customer what they want.

Modern manufacturing and service providers are using two philosophies in order to increase quality and the bottom line, profits. These concepts are Six Sigma and Lean Manufacturing. Six Sigma will help to reduce variation in the process with the use of the DMAIC method. Lean Manufacturing will seek to reduce waste which will translate in an increase in manufacturing flow, these is accomplished with the use of lean tools such as SMED, value stream mapping, standardize work, visual control, etc.

Lean Manufacturing

Lean Manufacturing is a management philosophy developed by the end of the 1950's from the Toyota Production System. Lean Enterprise focuses on the reduction of waste, cost and cycle time by understanding what the customer wants, what is valuable to the customer.

Value is what the customer is willing to pay and its defined by the ultimate customer[1]. Any activity that does not add value to the customer is considered waste and adds cost to the product or service, therefore, must be eliminated.

Lean uses simplicity and common sense to the manufacturing process. It focuses on operational details to continuously improve.

Lean uses five principles:

- Value specify what creates value from the customer's perspective.
- The value stream identify all the steps along the process chain. Like a road map the value stream map tool shows the road to start fixing individual process[2].
- Flow make the value process flow.
- Pull make only what is needed by the customer (short term response to the customer's rate of demand).
- Perfection strive for perfection by continually attempting to produce exactly what the customer wants.

The elimination of waste is the goal of Lean. Toyota defines three broad types of waste: *Muri, Mura and Muda. Muri* focuses on the preparation and planning of the process, or what work can be avoided proactively by design. *Mura* focuses on how the work design is implemented and the elimination of changes at the scheduling or operation level. *Muda* is the discovered after the process is in place and is dealt afterward.

Taiichi Ohno classified waste (muda) in seven categories [3] (Figure 1):

- 1: Overproduction
- 2: Inventory
- 3: Waiting
- 4: Motion
- 5: Transportation
- 6: Defects (Rework)
- 7: Over Processing



Overproduction is the worst of the seven wastes. It is making what is unnecessary and in unnecessary amounts. Occurs when you manufacture items for which there are no orders. Some of the causes for overproduction are: large lot, producing product in advance, large changeover and too much equipment. We can eliminate overproduction by balancing the line, go to one piece flow, using kanban, SMED, level production.

Inventory is caused by overproduction. This includes finished goods, assembly parts and raw materials. In lean manufacturing inventory is seen as a symptom of a sick factory. One of the best ways to begin finding waste is to look for retention points where inventory tends to pile up. Some of the causes of inventory are: acceptance of inventory as normal, poor equipment layout, long changeover times, large lot production, obstructed flow of goods and line unbalance. We can eliminate inventory by the redesign of the manufacturing cells, production leveling and using kanban system.

Waiting refers to both human and machine. Some of the causes for waiting are: obstruction of flow, poor equipment layout, capacity imbalance and a large lot production. We can eliminate waiting by leveling the production, improve layout, mistake proofing, single minute exchange dye (SMED).

Motion refers to movement that is not really needed to perform an operation. Its cause is: isolated operations, poor layout, lack of training, and increase in staff or workers hours. We can eliminate motion waste by switching to flow production, increase training, increase operator awareness about motion during an operation.

Transport is any transference of materials, parts, assembly parts, or finish goods from one place to another for any reason. Material handling is part of transportation. Transport becomes a waste due to poor layout and is not the intention of Lean to eliminate all transfer of goods within and between the processes, but we can shorten distance and reduce or eliminate retention points. Some of the lean methods to address transport are: U-shaped manufacturing cells, Flow production and Multiskilled workers.

Defects waste refers to defects itself, the cost of inspecting for defects, investigations of customer complaints. Some of the causes of defects are inspection at the end of the process, no standards for inspection, omission of standard operations. In order to eliminate defects we need to standardize the operations, mistake proofing devices, building quality at each process and flow production.

Over processing refers to operations and processes that may not be necessary. Over processing is caused by inadequate study of the processes or operations and incomplete standardization. To eliminate over processing we need to improve process design, review operations, standardize and automate process.

The heart of lean is found in the concept of continuous product and process improvement and the elimination of non-value added activities.

Lean implementation is, therefore, focused on getting the right things to the right place at the right time in the right quantity to achieve perfect flow, while minimizing waste and being flexible and able to change. The concepts of flexibility and change are principally required to allow production leveling, using tools like SMED.

SMED

Also known as quick changeover or rapid changeover, SMED is one of many lean tools for reducing waste in a manufacturing process. It was created by Shideo Shingo who was consulting for Toyota at the time. SMED relates to the changeover process that starts when it's made the last piece of the current lot and end with the first good piece of the next lot. This quick changeover will help to reduce production lot sizes and improve the manufacturing flow. Single minute refer to completing the changeover in less than ten minutes.

Among the benefits of SMED for the companies is increase flexibility. Now the companies can meet changing customer needs without increasing inventory. Allows for quick delivery, small lots mean less lead time and the customer doesn't have to wait for his product.

Better quality a successful changeover assures that the machine will start making good parts. The decrease in changeover time means the machine has more uptime and a higher productivity.

SMED involves three steps: separate internal and external activities, convert internal activities to external activities and streamline all activities [4].

- Step 1: Separate internal and external activities -the most important step for implementing SMED is distinguishing between internal and external activities [5]. Internal activities are activities that can be performed when the machine is stopped. External activities are performed while the machine is running.
- Step 2: Convert internal activities to external activities This involves two actions: examining activities to see whether any activities are incorrectly classified as internal; and converting internal activities to external activities.
- Step 3: Streamline all activities analyze in detail each activity and look for ways to reduce time on each one of them.

RESEARCH METHODOLOGY

The methodology which will be following in this study is the Lean Six Sigma project solving model called DMAIC (Figure 2) which stand for: Define, Measure, Analyze, Improve and Control.



Six Sigma Model

DMAIC is a problem solving method which has proven to be effective because it's structured and force the user to use data to quantify the problem, confirm the nature of the problem, find solutions and help to sustain the corrections implemented.

DEFINE

The purpose is to define the team and agree on what the project is. The activities to be developed as a team include: creating the project charter, getting customer data, reviewing existing data about the problem, drafting a high-level map of the process and setting up a plan with deliverables and timetable as to the work and meetings to complete.

The first step is to create a project charter. The information that will be captured is the description of the project, background, scope, benefits of the project in dollars, members of the team, strategic importance of the project and what the project deliveries are.

As said previously the customer is who defines what is of value to him and everything else is waste. A Voice of the Customer may be useful in the acquisition of data for the investigation. The term Voice of the Customer (VOC) is used to describe customers' needs and their perceptions of the product or service. VOC data helps an organization to decide what products and services to offer, identify critical features and specifications for those products and services, decide where to focus improvement efforts, get a baseline measure of customer satisfaction, identify key drivers of customer satisfaction.

In this project, the define step was completed with a Kaizen Blitz where different people from different backgrounds help to create the project charter. It is very important to have associates that work the machine as they are the owner of the process and will support any changes from this project.

Based on \$364/hr, three changeovers per month this project will represent a gain of \$78,624 annually.

Also the use of the brown paper (Figure 3) helps to define the current process step by step and to visualize what will be the future state of the process.

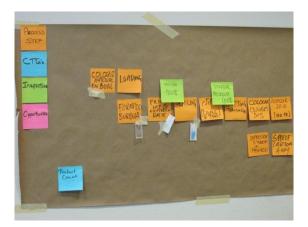


Figure 3 Brown Paper- Process Current State

MEASURE

The measuring phase is the gathering of data, understands the current process, and it serves the purpose of having a baseline to later compare the results after the implementation of improvements.

For this project the team went to the field (*gemba*) to start collecting the time of all the activities that were delineated in the define phase.

ANALYZE

The purpose of this phase is to make sense of all the information and data collected in the measure phase, and to use that data to confirm the source of poor quality, defects, etc. The challenge that all teams face in the analyze phase is sticking to the data, and not using their own experience and opinions to reach conclusions about the root causes of problems.

For the analyze phase the project started doing the three steps of the SMED tooling, did a brainstorming to start determining which activities are internal and which are external. Then when to understand which of the internal activities can be converted to external activities and finally streamline all activities.

IMPROVE

The purpose of the improve phase is to make changes in the process that will eliminate the defects, waste, cost, over processing, waiting unnecessary motion, etc. The team must be sure that the changes they make must affect the activities they enumerated in the analyze phase. Here the team goes out and try all the improvements that came from the analyze phase and start collecting data of all activities with the improvements. With the data gathered they start comparing against the baseline data they collected in the measure phase and see if the improvements reduce the changeover time.

CONTROL

The purpose of this phase is to make sure that any gains identified will last. That means creating procedures and work aids that will help people do their jobs differently from now on. In Control phase the new, improved procedures should be documented, train everyone, set up metrics for tracking the new process, hand-off ongoing management to the process owner, and complete the project documentation. The Control Tool used in this project is the standardized work sheet and a checklist. The standardized worksheet helps in two ways: standardize the work between the various associates that performed the changeover and serve the purpose to be a guide to train new personnel. The checklist will remind the associate all the activities and the order they have to perform them,

this way we can reduce errors of associates that forget to perform a step.

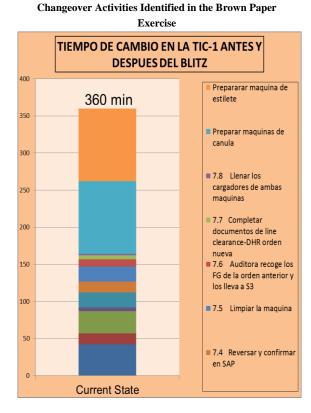
RESEARCH RESULTS

Currently the changeovers on the Tic#1 machine on average take 6 hours and use one setup. The standard changeover time for this machine is four hours. The utilization of the machine is 75%, with a 20% of machine utilization wasted. The OEE target for the TIC's machine is 85%. Annually there is a cost of \$79 k wasted due to loss capacity.

This project with the use of the SMED tool will increase by 20% the machine utilization and this will increase the machine OEE.

After coming with a list of the activities for the changeover and data collected of these activities the process takes an average of 360 minutes to complete the changeover (refer to Table 1).

Table 1



The brainstorming held during the analyze phase brought the following improvements. It was recommended to use a second set up during the changeover. One setup to perform the changeover for each machine. That way the two machines can be worked in parallel and not sequential like the actual process. Train the process auditor to complete the paper work; return of material that remains from previous order and issue of materials for the next order these activities were converted to an external activity, before, it was done as an internal activity. Prepare a toolkit with the parts that need replacing during the changeover. Prepare a toolbox with the tools most needed during the changeover. With these changes a checklist (see Figure 5) was prepared.



Figure 4 Toolkit with Tools Needed for the Changeover

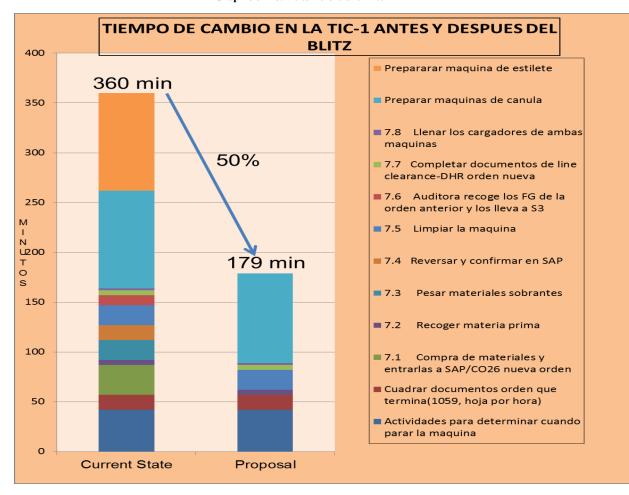


 Table 2

 Graphic of Activities Before and After

Actividad	Asociado	\checkmark	Actividad	Asociad
			7.1 Compra de materiales y	
Verificar cantidades en el			entrarlas a SAP/CO26 nueva	
CO26	Setup		orden	Audito
 Evaluar momento para parar	Setup			
Parar maquina de canula	Setup			
Continuar con maquina de				
estilete hasta terminar				
acumulado	Setup			
 Parar maquina de estilete	Setup			
Cuadre BDM1059/Hoja por				
 hora				
 6.1 BDM 1059	Setup			
6.2 Cuadrar orden en SAP	Setup			
	Setup			
 6.3 Hoja por hora	Setup			1
Comienza Line Clearance				
7.2 Recoger materia			7.3 Pesar materiales	
prima	Setup		sobrantes	Audito
	Setup/		7.4 Reversar y confirmar en	
 7.5 Limpiar la maquina	Auditora		SAP	Audito
de line clearance-DHR			7.6 Auditora recoge los FG de	
orden nueva	Setup		la orden anterior y los lleva a S3	Audito
7.8 Llenar los cargadores				
 de ambas maquinas	Setup			-
 Termina Line Clearance				
Mover camaras en maquina			Mover camaras en maquina de	Setu
 de canula	Setup		estilete	Auxili
				Setu
 Moldear canulas	Setup		Moldear estilete	Auxili
Medir piezas moldeadas en	Onter		Medir piezas de estilete en hoja	Setu
 hoja de Excel Ajuste de camaras de	Setup		de Excel Ajuste de camaras de maquina	Auxili Setu
Ajuste de camaras de maquina de canula(offset)	Satur		Ajuste de camaras de maquina de estilete(offset)	Auxili
 naquina de canuia(onset)	Setup			Setu
Madir al large de actilate			Medir el largo de estilete	Auxili
 Medir el largo de estilete			· · · · · · · · · · · · · · · · · · ·	
 Arranco maguina de canula.				Setu

Figure 5 Checklist

With the implementation of these ideas we made a changeover and the changeover time was reduced to 179 minutes (see Table 2).

CONCLUSIONS

After completion of the SMED process a reduction of 50% in the changeover time was

achieved. The setup has a checklist to remember all the activities. The elimination of waste motion was achieved as the setup had to go to the tool room to get spare parts for the changeover; now the parts that he needs are at the site.

It is recommended for future project to pass through the SMED tool again for this machine in

order to continue reducing the changeover time. I found that the tool is very helpful, but needs to be repeated two or three times with the purpose of reducing the time and achieve the goal of less than ten minutes.

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