Changeover Process Optimization for a Medical Device Manufacturer in Haina, Dominican Republic.

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Abstract *— The medical device industry has the critical mission of saving and sustaining lives of patients being affected by chronical diseases. To these companies, having more available time to produce will enable and facilitate treatment for more patients that currently are left aside due to lack of medical solutions. Time invested on change over endeavors can be directly translated into revenue or productivity loss, as events of high duration decrease time available for production of sealable finished good units. This project assisted Baxter Healthcare's subsidiary located in Haina, Dominican Republic on implementing Single-Minute Exchange of Dies (SMED) methodology to enable Changeover time reduction of 80% vs baseline and augmenting in +25% current production capacity. The materialization of this project provides a practical example of a SMED implementation within the Medical Device Industry.*

Key Terms *— Change Over Reduction, Internal vs External Process Activities, Productivity Augmentation, Single-Minute Exchange of Dies (SMED).*

INTRODUCTION

The medical device industry has the critical mission of saving and sustaining lives of patients being affected by chronical diseases. To these companies, having more available time to manufacture their products will enable and facilitate treatment for patients that currently are left aside due to lack of medical solutions.

Its beyond revenue, it is about saving lives: commitment on value creation for customers and relentless continuous improvement, which entails reduction of process wastes and flow creation becomes the purpose of existence and daily drive.

In the manufacturing industry, changeover is known as the efforts required to convert a production line configuration or machine set up from producing one product to another. Time invested on this endeavor can be directly translated into revenue or productivity loss, as changeovers of high duration decrease time available for production of sealable finished good units.

Pursuing reduction or minimization of the time invested on changeover duties has multiple collateral benefits on areas such as inventory management, where stockless production drive higher turnover rates, ending on freeing floor space from the facility. In addition, it facilitates preservation of goods as they are not lost through deterioration or expiration as outcome of low movement.

By implementing a Change Over Process Optimization, companies improve their Industry Leading Performance Key Indicators augmenting productivity and reducing costs. To achieve these results, Single-Minute Exchange of Die (SMED) methodology will be implemented as developed by Taiichi Ohno and Shigeo Shingo, former managers of the machine shops at Toyota.

BACKGROUND

Baxter Healthcare's subsidiary located in Haina, Dominican Republic, invest 33% of available time for production on changeover activities. Despite the magnitude of time invested, set up defect rates are not under control and present themselves with high frequency during regular operations. Therefore, causing re-processing, higher operational costs and may put at risks meeting the patient's expectation of the well function of the therapies received for their care.

By implementing a Change Over Process Optimization utilizing Single-Minute Exchange of Dies (SMED), Baxter Inc. Medical Device Manufacturer in Haina, Dominican Republic, improved its industry's leading performance key indicators, augmented productivity, and reduced costs. In addition, it impacted favorably patient safety and quality by the elimination of failure modes with direct mayor product/process quality impact.

SMED methodology focused on elements from the changeover process by separating or converting them (moving them external to the changeover) and then streamlining any remaining elements (completing them faster, easier, or in parallel with other elements).

LITERATURE REVIEW

Changeover is known as the efforts required to convert a production line configuration or machine set up from producing one product to another. Changeover can be divided into the 3 stages: Clean-up , Set-up and Start-up [1]:

- Clean-up the product, materials, and components from the line. It may range from minor, if only the label of a package is being changed (for example from an English to a Spanish label) to major, requiring complete disassembly of the equipment, cleaning and sterilizing of the line components in the case of an injectable pharmaceutical product.
- Set-up is the process of converting the equipment. This may be achieved by adjusting the equipment to correspond to the next product or by changing non-adjustable "change parts" to accommodate the product. Typically, it will be a combination of both.
- Start-up is the time spent fine tuning the equipment after it has been restarted. It is characterized by frequent stoppages, jams, quality rejects and other problems. It is generally caused by variability in the clean-up and set-up or by variability in the product or its components.

Single-Minute Digit Exchange of Die (SMED) is one of the many lean production methods [2] for reducing waste in a manufacturing process. It provides a rapid and efficient way of converting a manufacturing process from running the current product to running the next product. This rapid changeover is key to reducing production lot sizes and thereby reducing uneven flow (Mura/waste), production loss and output variability.

The term "single- minute" does not mean that all changeovers and startups should take only one minute, but that they should take less than 10 minutes (in other words, "single-digit minute") [3]. Closely associated is a yet more difficult concept, One-Touch Exchange of Die, (OTED), which says changeovers can and should take less than 100 seconds. A die is a tool used in manufacturing. However, SMED's utility is not limited to manufacturing.

Changeover historical backgrounds take us to when Frederick Taylor analyzed non-value-adding parts of setups in his 1911 book, Shop Management (page 171) [11]. However, he did not create any method or structured approach around it.

Frank Bunker Gilbreth - a well-known American scientific - studied and improved working processes in many different industries, from bricklaying to surgery. As part of his work, he also investigated changeovers. His book Motion Study, also from 1911, [13] described approaches to reduce setup time.

In the 1915 publication Ford Methods and Ford Shops [12], setup reduction approaches were clearly described. However, these approaches never became mainstream. For most parts during the 20th century, the economic order quantity was the gold standard for lot sizing.

The Just in Time (JIT) workflow of Toyota had this problem of tools changeover took between two and eight hours, Toyota could neither afford the lost production time nor the enormous lot sizes suggested by the economic order quantity.

On a trip to the US in 1955, Taiichi Ohno observed Danly stamping presses with rapid die change capability. Subsequently, Toyota bought multiple Danly presses for the Motomachi plant. And Toyota started to work on improving the changeover time of their presses. This was known as Quick Die Change, or QDC for short. They developed a structured approach based on a framework from the US World War II Training within Industry (TWI) program, called ECRS (Eliminate, Combine, Rearrange, and Simplify). Over time they reduced these changeover times from hours to fifteen minutes by the 1960s, three minutes by the 1970s and then just 180 seconds by 1990s. During the late 1970s, when Toyota's method was already well refined, Shigeo Shingo participated in one QDC workshop. After he started to publicize details of the Toyota Production System without permission, the business connection was terminated abruptly by Toyota. Shingo moved to the US and started to consult on lean manufacturing. Besides claiming to have invented this quick changeover method (among many other things), he renamed it Single-Minute Exchange of Die or, in short, SMED. The Single-Minute stands for a single digit minute (i.e., less than ten minutes). He promoted TPS and SMED in US [4], [5].

Regarding implementation, Shigeo Shingo recognizes eight techniques that should be considered in implementing SMED [6]:

1. Separate internal from external setup operations
2. Convert internal to external setup
3. Standardize function, not shape
4. Use functional clamps or eliminate fasteners altogether
5. Use intermediate jigs
6. Adopt parallel operations
7. Eliminate adjustments
8. Mechanization

External setup can be done without the line being stopped, whereas internal setup requires that the line be stopped. He suggests [7] that SMED improvement should pass through four conceptual stages:

1. Ensure that external setup actions are performed while the machine is still running.
2. Separate external and internal setup actions, ensure that the parts all function and implement efficient ways of transporting the die and other parts.
3. Convert internal setup actions to external.
4. Improve all setup actions.

According to Vorne Manufacturing Improvement Solution Maker [8], the fastest path to improved changeover times is typically through non-technical improvements, such as creating standardized work instructions, marking down known settings on equipment, and displaying real-time metrics.

In SMED, the changeover process is broken into a sequenced list of steps called elements. The objective of SMED is to remove as many elements from the changeover process as possible by separating or converting them (moving them external to the changeover) and then streamlining any remaining elements (completing them faster, easier, or in parallel with other elements).

PROBLEM STATEMENT

Implement a Change Over Process Optimization utilizing Single-Minute Exchange of Dies (SMED) to enable Baxter Inc. Medical Device Manufacturer in Haina, Dominican Republic, improve its industry leading performance Key Indicators by augmenting productivity and achieving cost reduction.

OBJECTIVES

The aim achievement after implementing the project is to benefit Baxter’s Industry Performance by:

- Gaining a Change Over time over >15% versus baseline
- Augmenting productivity by over > 15% versus baseline
- Reflecting cost reductions derived from SMED implementation > USD$20,000.00

- Gaining alignment to Industry Performance: by having no dedicated special crew required to complete Manufacturing Line set up.

SIGNIFICANCE

The materialization of this project will provide a practical example of a successful SMED implementation within the Medical Device Industry. It will drive Baxter Healthcare Subsidiary in Haina, Dominican Republic to increase its productivity and enable the possibility of an additional 25 million units to be sold around the glove reaching patients with critical conditions.

METHODOLOGY

Objectives will be achieved by implementing the following basic steps to reducing changeover using the SMED system:

- Observing the current methodology
- Separate the internal and external activities. Internal activities are those that can only be performed when the process is stopped, while external activities can be done while the last batch is being produced, or once the next batch has started
- Convert (where possible) internal activities into external ones
- Streamline the remaining internal activities, by simplifying them. Focus on fixings – Shigeo Shingo observed that it's only the last turn of a bolt that tightens it – the rest is just movement
- Streamline the external activities, so that they are of a similar scale to the internal ones
- Generate improvement charts to demonstrate before and after as well as control charts to understand changeover quality adherence
- Quantity time saved and re-allocate resources to production to enable set-up crew headcount reduction
- Calculate savings of optimizations made

RESULTS

In conjunction to SMED Change Over Optimization, 2 new systems were being implemented that converged and interacted with Change Over activities:

- Digital Device History Record (DHR) - its implementation eliminated the printout requirement for 60% of current manual forms. System implementation experienced serious setbacks due to incorrect data upload and process flow configuration, impacting Change Over process triggering manual print outs of the 100% of forms.
- Controlled Forms Management System: its implementation allowed on demand print out of regulated forms by stamping the date, batch and user that printed the regulated form to be used. System implementation brought significant noise to data collection for the first 3 weeks as system froze constantly delaying the manual forms printing process and it did not allow multiple forms or quantity printing functionality.

Data noises were extracted from the analysis. By implanting SMED, the Change Over process reflected a material optimization in which we can now observe the Change Over time being 1.5 – 2 Hrs. (80% reduction versus baseline) See Table 1. This was achieved by the application of SMED principle entailing to reduce internal activities by exchanging them for external ones (see Table 2).

In this regard, we can notice that 8 out of 13 activities were transformed to external, which translated into a 62% internal to external process conversion (see Table 1).

Internal to external process conversion brought a moderate improvement on resource utilization for the Shift A/B and eliminated the need to maintain resources from Shift C fully dedicated to Change Over activities, turning Shift C into available time for production augmenting in +25% current capacity (see Table 1).

Table 1
SMED Implementation Results Summary

Table No. 1 - SMED Implementatation Results Summary		
CRITERIA	BEFORE	AFTER
Change Over Events Examined	0 - 25 weeks	26 - 30 weeks
SMED - External Process Steps	1 External / 13 Total Process Steps	9 External / 13 Total Process Steps
SMED - Internal Process Steps	12 Internal / 13 Total Process Steps	4 Internal / 13 Total Process Steps
Set Up Time Spent	6 Hrs - 8 Hrs	1.5 Hrs - 2 Hrs
Resource & Resource Capacity	Shift C - 8 resources fully dedicated to change over activities. Under-utilized by 44%. Shift A / B - 33 resources with 11% available capacity.	Shift C - 0 resources assigned. Shift A / B - 33 resources with 4% available capacity. Resource workload re-balanced to maximize capacity utilization.
Available time for production / Day	Shift A - 7 Hrs, Shift B - 7 Hrs.	Shift A - 7 Hrs, Shift B - 7 Hrs, Shift C - 7 Hrs.
Capacity Optimization		+25%
Cost Savings		USD 83.5K Annually USD$ 43.7K Transportation *USD$ 39.8K Salary & Benefits * Resources were engaged to

The removal of Change Over activities on shift C and their diversion to shift A/B resulted on the elimination of 8 positions within the organization. The elimination of this 8 Positions represented a cost saving of USD$83.5K annually (see Table 1). The 8 resources were re-allocated to backfill open roles within Shift B hence no impact to the workplace was reflected.

In addition, Plan versus Actual Change Over Performance also reflected a material normalization minimizing variation versus Goal landing on error free Change Over events increase, augmenting process reliability (see Graph 1).

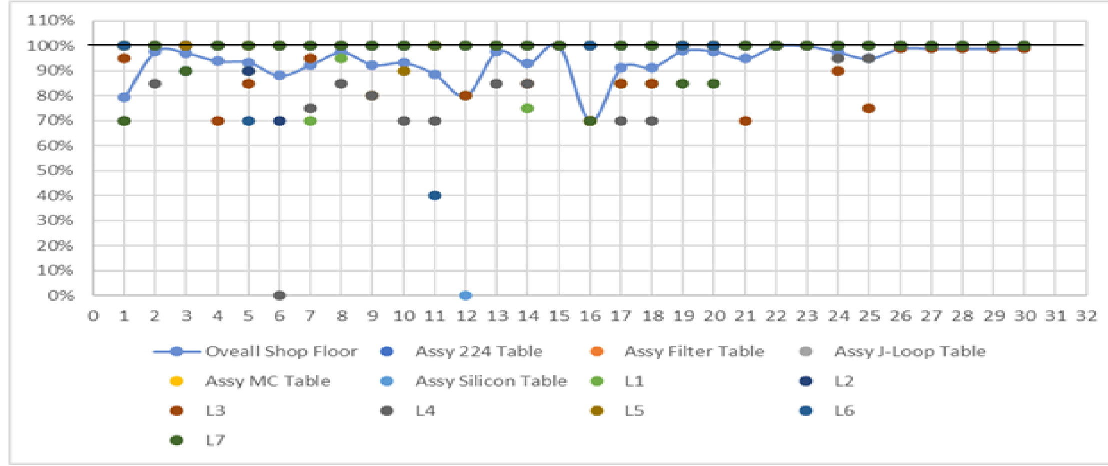
Discussion

Outcomes of the implementation of this project exceeded original expected results: applying SMED resulted on a 80% Change Over time reduction, 25% capacity gains reflected on more available time to produce, 80% Failure Mode reduction per Change Over event, minimization of idle capacity of current resources and resulted on Annual USD83.5K in cost reductions for the company.

These results are aligned with the findings of prior efforts such as Shigeo Shingo, who created the SMED approach, that claimed [9] that in his data collected between 1975 and 1985 the average setup times he had dealt with had reflected a 40 times improvement versus the time originally required. Another example was shared by a Project Manager within Zenith Technologies [10] – a company proving engineering solutions to industrial market. One Life Science company he worked with reduced their changeover times from 60 minutes down to just 30 minutes – a 50% improvement.

Table 2
SMED Internal vs External Process Elements Assessment

NO.	PROCESS ELEMENTS	BEFORE	AFTER
1	Stablish conveyor Time Stop per line, accounting for manufacturing complexity and Shift event's.	I	I
2	Rectify applicable additional documentation is ready for Cut Of Batch (COB), First Of Codes (FOC), MOCKs and Reworks (RWKs) when apply.	I	E
3	Print Bill Of Material (BOM), Specifications (SPECs) and Product Control Specification (PCS).	I	E
4	Rectify existence of Panel Settings and Printing Plate is released.	I	E
5	Rectify printing recipe is loaded and available on Urania Machine.	I	E
6	Compile physical DHR package for applicable manufacturing lines and rectify completion.	I	E
7	Complete Material Kits dispatch	E	E
8	Receive Material Kits dispatch	I	E
9	Print Material Kit identification labels	I	E
10	Set manufacturing aids and peripherals	I	I
11	Set solvent dispensers	I	I
12	Execute conveyor clean up from old materials / feed with applicable materials.	I	I
13	At set up, complete Device History Record (DHR) applicable forms and ensure correctness.	I	E
14	Internal Total Count	12	4
15	External Total Count	1	9
	PROCESS ELEMENTS - GRAND TOTALS	**13**	**13**



Graph No. 1 Plan versus Actual Change Over Performance (Error Free Process)

Graph 1
Plan vs Actual Change Over Performance

CONCLUSIONS

Although a material process optimization was experienced as it was previously detailed, the “single-minute” aimed state was not achieved. Shigeo Shingo’s ideal Change Over time should take less than 10 minutes (in other words, "single-digit minute")[3].

Further optimizations could be explored to narrow the current gap and achieve Shigeo Shingo’s ideal Change Over time: the optimization of the Device History Record (DHR) currently accounting for over 30 forms within it; the complete digitalization of the Digital Device History Record (DHR) can also be pursued; replace obsolete machinery that requires a significant amount of set up time and resources, to name a few.

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