Improve Major Changeover Procedure in MK0431AR Coating Area

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Abstract

Today, most plants are running multiple products per line per day, including varieties of the same products, requiring many changeovers with the intense pressures to boost production efficiency, meet increasing consumer demands, and reduce production cost. The intent of this project was to reduce the time required to make a major changeover of Merck Arecibo Operations new product, MK0431AR, with the goal of increasing capacity. Reducing the changeover time is important because, in addition to increasing capacity and reducing costs, it allows the use of innovative production techniques. Before improvements, the major changeovers took approximately 6.5 hours. This time was reduced to 4.2 hours, exceeding the original target of 4.5 hours. The methodologies used to achieve this reduction were SMED and Toyota Kata. Also, as part of the project, the dust collector filter change procedure was improved to reduce their change frequency and time.

Project Charter

Business Case

The new product of Merck Arecibo Operations MK0431AR is a tablet containing two oral antidiabetic medications used in the management of type 2 diabetes: sitagliptin and metformin hydrochloride extended-release. To add the sitaglipting, a precision coating process is used. Currently the dosages of this product are 50/1000Mg, 100/1000Mg and 50/500Mg (Sitaglipting/ Metforming), the same coaters are used for each of the dosage; for this reason, for every change of dosage or campaign length (12 lots), a major changeover is required. For Merck is imperative to reduce the major changeovers to increase manufacturing area capacity, reduce cost, and integrate the best compliance posture on the industry to be competitive and keep the full demand requirements in Merck Arecibo Operations.

Problem Statement

During January through June 2013, MK0431AR major changeover (major cleaning and set up) in the coating area has taken 6.5 hours for API coating versus a goal of 5 hours. Also, as a safety requirement, a new method to replace the filters of the dust collector used by the coater has been established. The bag in bag method was established, which requires to do the filter change steps through a plastic bag to avoid exposure to the sitagipting; doing this takes longer and is harder to complete than the method used before without the bags. Taking in consideration that the filter change process disabilities the MK0431AR coater an increment of 6 hours of downtime per filter change has been observed.

Goal Statement

Achieve and sustain major changeover of 4.5 hours with only 2 operators. Improve filter change process to be done during major changeovers (4.5 hours).

Current State

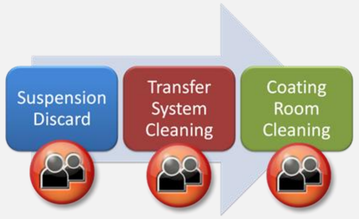

Figure 1
Major Changeovers Block Diagram

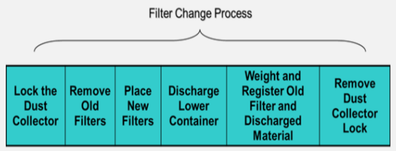

Figure 2
6 Main Steps of Filter Change

Performance Before Improvement

To simplify the analysis of the major changeovers, the process was divided in 3 major buckets: suspension disposal, transfer system cleaning and coating room cleaning. The calibration process was removed of the changeover because it is counted in the run time. This task takes an average of 15 minutes. The performance for Sep 21 was 4 hours and 41 minutes. Figure 3 shows 4 major changeovers time before the start of the project, subdivided in the 3 main buckets. On the other hand, the total time of the dust collector filter change during the first observation was 8.1 hours. Subdividing the process for one filter of the four required in the change, a Pareto chart was made. Figure 4 shows the Pareto Analysis, from which it can be seen that the two tasks that took more time were the twist and cut process (26.4%) and placing the second filter (25.4%).

Figure 3
Major Changeovers Performance

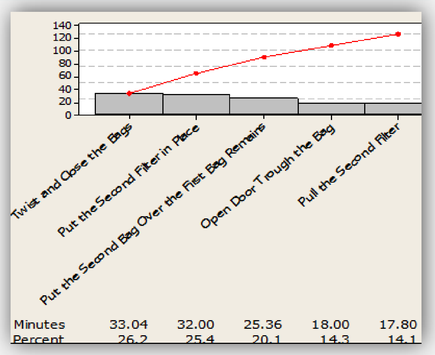

Figure 4
Pareto Of Filter Change Steps Time

Analysis

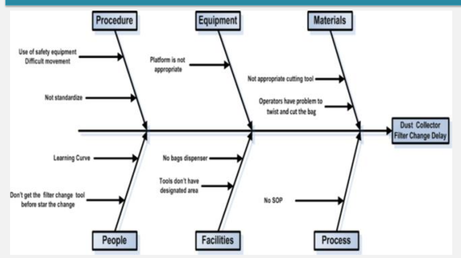

Figure 5
Fishbone for filter change

To find the root cause of the filter change and major changeovers delays, two separate fish bones analysis were made. In Figure 5 the fishbone of the filter changes is presented; the most significant problem is the absence of a SOP.

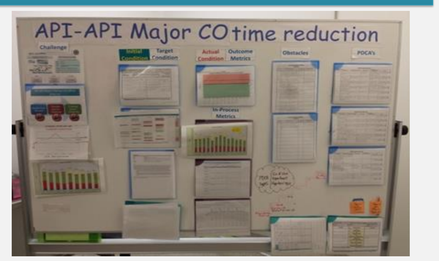

Image 1
Toyota Kata Story Board

A kaizen was made to analyze and improve the changeover forms. A total of 5 forms were revised and changed to remove no applicable steps and reorganize valid ones. Image 2 shows the working team of the Kaizen, a representation of Quality, Safety and Manufacturing areas were present.

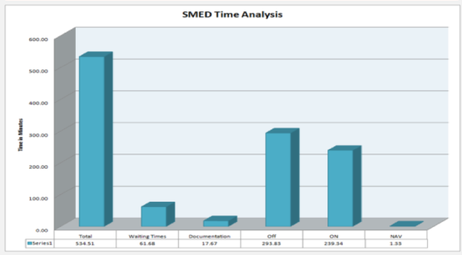

Figure 6
SMED Analysis for Major Changeover

Image 2
Major Changeover Form Kaizen

Improvements

Filter Change

New tool and equipment were purchased to reduce the time process. The most significant are the bags and the platform. The total overall time reduction of 2.9 hours was achieved after the training and the use of the new tools and equipment. Also, a significant cost reduction was obtained using the thinner and cheaper bags. Figures 8 and 9 describe the cost of the filter change, before and after improvements. The following list, are the new equipment's and materials bought to improve the process: Flashlight ,New platform, New cutting tool, Bag dispenser, Thinner bag.

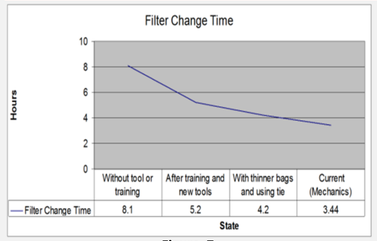

Figure 7
Filter Change Current Performance

Filter Change Material and Labor Cost				
		Quantities		
Item name	Unit Price	needed	Total	
Bag Tie	$ 1.50	8	$ 12.00	
Bibo polyethylene bag for cartridge	$ 39.00	8	$ 312.00	
Fibra web filter	$ 151.00	8	$ 1,208.00	
Protective Mask	$ 34.00	2	$ 68.00	
Salaries ($15 hr for 5hr)	$ 75.00	2	$ 150.00	
Total				$ 1,750.00

Figure 8
Filter Cost Before Improvement

Image 3
New Tools

Filter Change Material and Labor Cost			
Item name	Unit Price	Quantity Needed	Total
Bag tie	$1.50	16	$24.00
Thinner Bag for filter	$0.35	16	$5.60
Fibra web filters	$151	8	$1,208.00
Mechanical salary ($15.00*4hrs)	$ 60.00	2	$120.00
Total			$1,357.60

Figure 9
Filter Cost After Improvement

Major Changeover

As for the major changeovers, after completing all the improvements and establishing the standardize work, the time required for the major changeover was reduced to only 4.3 hours, as shown in Figure 13. Other benefits of the project are:

Eliminate de-foaming impact by preparing the suspension during run time, Produce 76 API coated lot more per year with absorption of $999,932 , and Financial Benefit in labor cost of $31,574 per year.

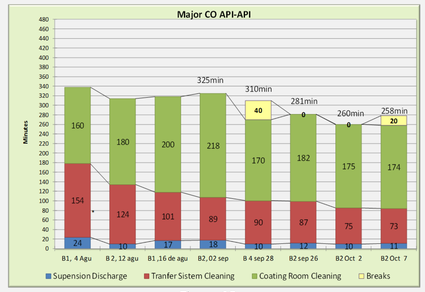

Figure 10
Filter Cost Before Improvement

Image 4
Standardize Work and Time Collection Table Placed in The Coating Room

Conclusion

After the completion of this project, it was learned that there are many opportunities in the production areas. The important thing is to focus on specific one and follow a direction. Regarding the tools used, as this is the first improvement tool worked with Toyota Kata in Merck Arecibo, achievements found could be an example of the power of this tool, and how it can be combined with Lean Six Sigma tools to improve any process. Another important lesson is the importance of having a well diversified group, to analyze and make changes. In other words, have the right people, in the right place, at the right time.