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.*

Key Terms— *Changeovers, DMAIC, Improvement, SMED, Toyota Kata, Waste*

INTRODUCTION

Project Charter of Improve Major Changeover Procedure

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).

Project Scope

In Scope: MK0431AR coating area major changeover procedure, including the coaters filter change

Out Of Scope: Minor changeovers procedure

Overview of the Process

SIPOC

The SIPOC were used to describe the supplier, input, process, output and customer of the filter change and major changeovers. Figure 1 shows the SIPOC of the filter change process. The basic steps of the filter change are presented in the process area. Figure 2 shows the SIPOC of the filter change process.

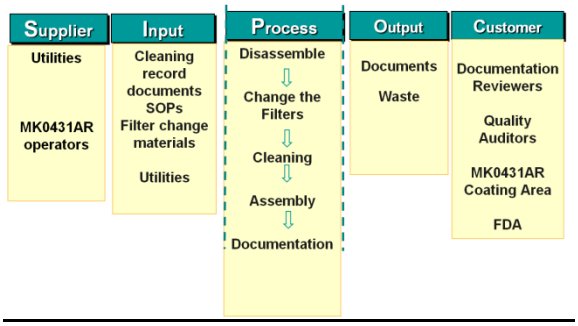


Figure 1
SIPOC of Filter Change

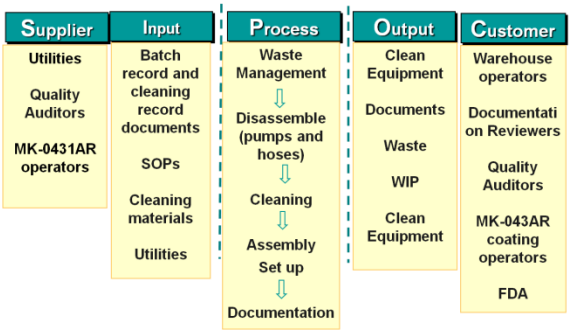


Figure 2
SIPOC of Major Changeovers

Filter Change Process Steps

The filter change process consists of 6 basic steps. Figure 3 present the order of the steps and the activities required in each of them. For the project, all the steps were analyzed. The filter change occurs every 100 hours of coater runtime.

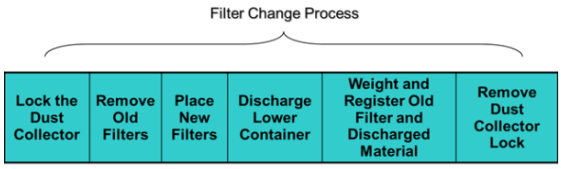


Figure 3
Filter Change Steps Order

On other hand, before improvement, major changeovers consisted of 4 steps; after improvement, the calibration was moved to the run time process. Figure 4 shows the 3 main steps of the major changeovers, the order and the number of operators in a block diagram.

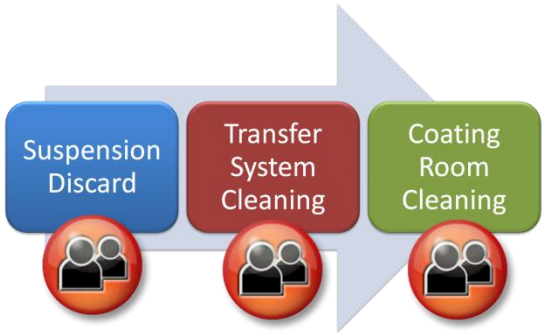


Figure 4
Major Changeovers Block Diagram

Data Collection Plan

The process time and process steps data were collected using observation during the process. After the improvement, the time was collected using forms.

LITERATURE REVIEW

SMED Analysis

The principal idea of SMED (*Single-Minute Exchange of Die)* is divide the activities in external and internal activities. It should be understood that internal preparation are activities whose implementation require to stop the machine or equipment, while the external include all activities that can be performed while the machine is running.

After placing the task in the new order, all of them should be standardize, especially the operations of preparing the equipments, tools and materials. Reducing changeover times will not only help the organization to improve quality and flexibility, but it will save thousands and sometimes even tens of thousands of dollars per hour [1].

Toyota Kata to Accelerate Changeovers Improvements

The concept that Toyota Kata follows is to create a daily basis routine with 5 key questions. This routine allows project managers, or "Learner", to have greater support from their sponsors, who are often their "coach" or leader, while developing their skills at the same time. As in sports and music, practicing should be done under periodic observation and guidance of an experienced coach. Without coaching, people lose their way and don't practice in the right pattern, or practice ineffectively [2].Undoubtedly, the use of this new concept allows better opportunity to project and to achieve the goals in the proposed date.

MEASURE AND ANALYSIS

Process Current State

Filter Change

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 5 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%). Each dust collector contained 4 ducts with 2 filters on each one, for a total of 8 filters being replaced at every filter change.

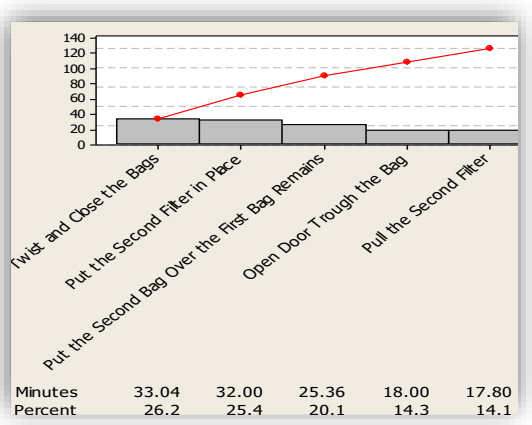
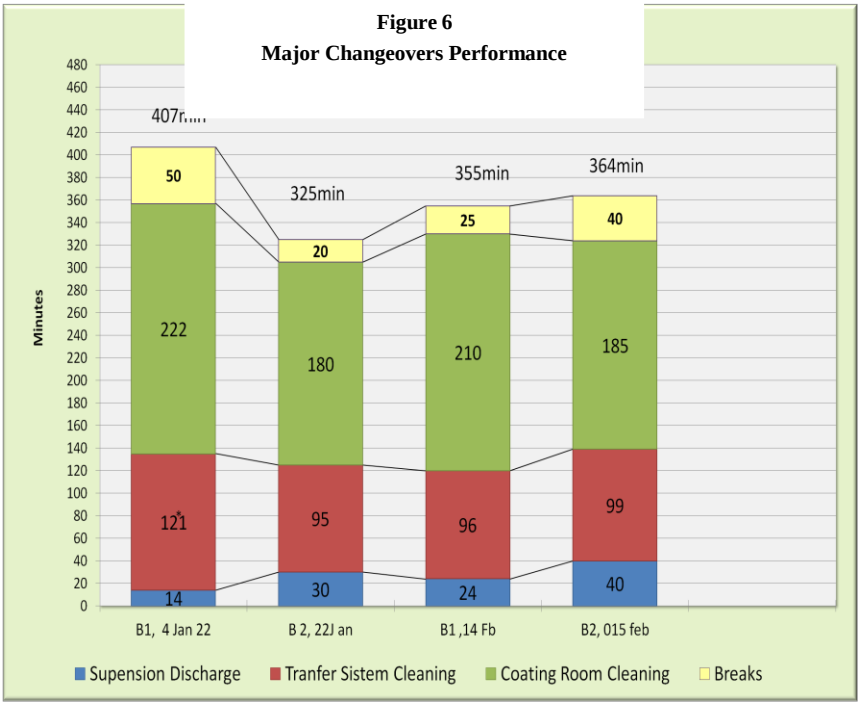


Figure 5
Pareto Of Filter Change Steps Time

Major Changeovers

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 6 shows 4 major changeovers time before the start of the project, subdivided in the 3 main buckets.

Figure 6
Major Changeovers Performance



Measure Process

Capacity Impact

A capacity impact was made to understand the economic impact of the filter change. A total of .241 lots were not produced each time the maintenance was done, for personal and time limitations. The total absorption cost per year if the filters are changed every 100 hours is $216,373. Table 1 show the capacity impact calculation based in the demand.

Fishbone

To find the root cause of the filter change and major changeovers delays, two separate fish bones analysis were made. In Figure 7 the fishbone of the filter changes is presented; the most significant problem is the absence of a SOP. In Figure 8 the major changeover fishbone is presented [3].

Process	Target Time(hrs)	Demand (feb-dec)	Contribution %
CT 50/500 mg	18.5	20	0.045146727
CT 50/1000 mg	12	329	0.742663657
CT 100/1000 mg	16.5	94	0.212189616
Average CT	13.248307		

Overtime Cost	
Salary	$15.60
Overtime salary (1.5)	$23.40
Hours needed in every filter change	5
Operators needed	2
Overtime cost for each filter change	$234.00

Cpacity decrease	
Average Run Time	13.24
Change Over Time	7.5
Average CT	20.74
Hours needed in every filter change	5
Capity decreas in lots	0.241

Only 2 coating rooms can run with 4 operators

Process Contribution =Process demand/∑Demands
Weighted Average Run Time= ∑(Process Contribution*Process RT)
Average RT=(18.5hrs*.04514+12hrs*.7242+16.5hrs*.212220) =13.24hrs

Over time cost= Average Hr salary * 1.5 = $15.6*1.5= $23.40
Overtime cost per filter change = Overtime cost * Hrs needed to change the filters = $23.4*5 = $234.00

Average CT **=Weighted Average RT + Change Over Time = 13.24hr+7.5 hrs = 20.74hrs**

Approximated Capacity Decrease = Hours Needed to 1 lot per filter change

Table 1
Calculation of Capacity Impact of Filter Change Process

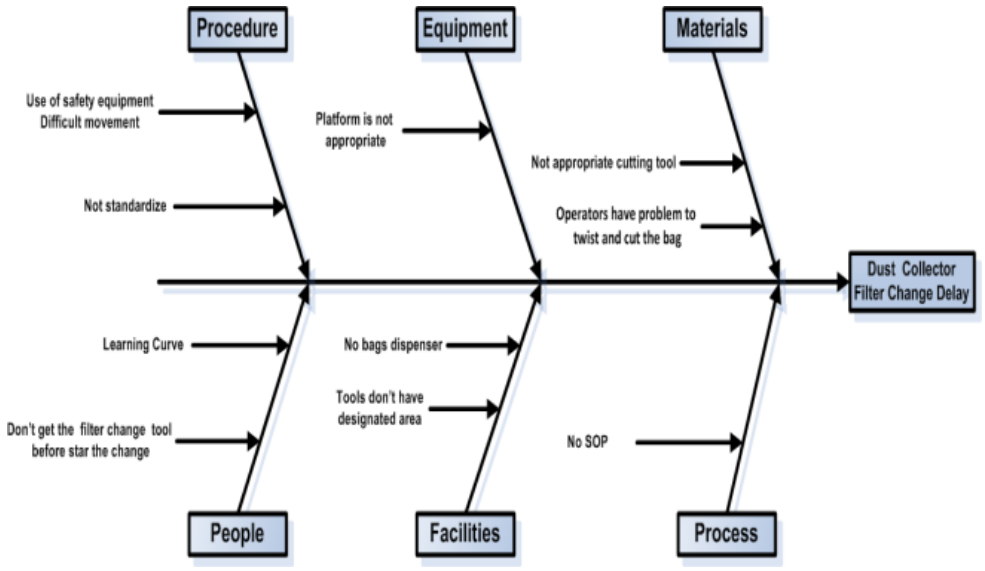


Figure 7
Filter Change's Fishbone

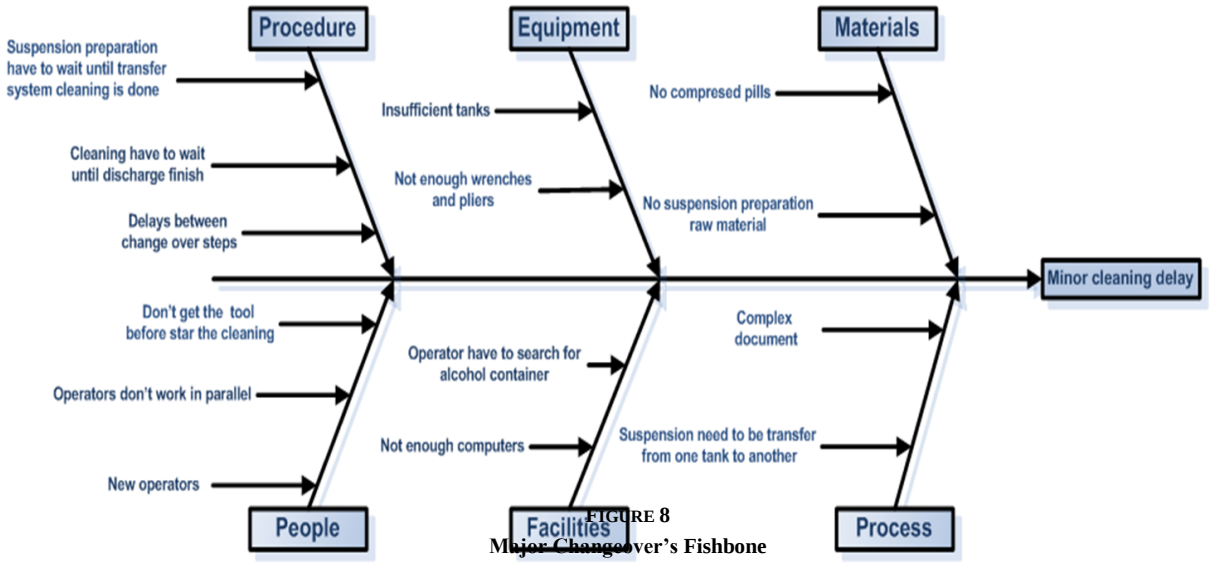


FIGURE 8
Major Changeover's Fishbone

Image 1
Major Changeover Kata Story Board

5 Whys

After finishing the fishbone analysis for each of the processes, a 5 Whys and possible solution exercise was made for the filter change process to find the root causes. On other hand, for the major changeover, the possible solutions and root cause were worked using the obstacle and PDCA section of the improvement Kata story board. The obstacles are the items preventing the achievement of the target condition, and the PDCA (plan, do, check and act) are experiment used to remove the obstacles. Image 1 shows the Toyota Kata story board, placed in the coating area of MK0431AR. In image 2 a zoom of the obstacle and PDCA area of the board is presented.

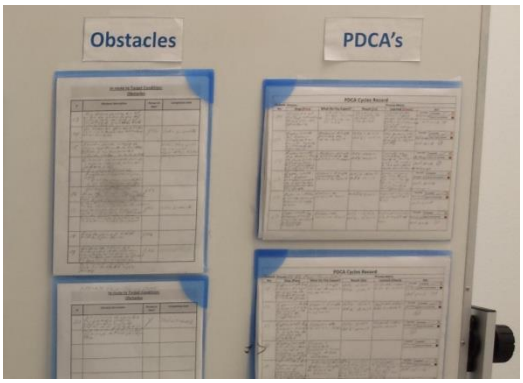
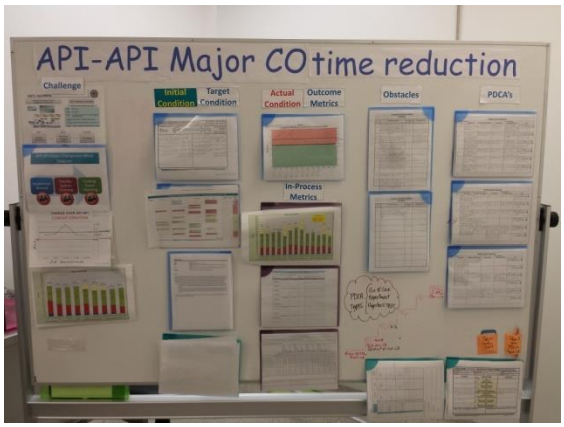


Image 2
Obstacle and PDCA Section of the Story Board



Prioritization

Prioritizations for the major changeover were established by the target condition in the Kata story board. On the other hand, the prioritization of the dust collector filter change was established using a Pareto chart.

SMED Analysis

Using the SMED system, it was determined the time of the tasks and which ones can be done outside the changeover time as well as the time used for

documentation and waiting time. Standard time is 279.8 minute with allowances of 17% based on ILO

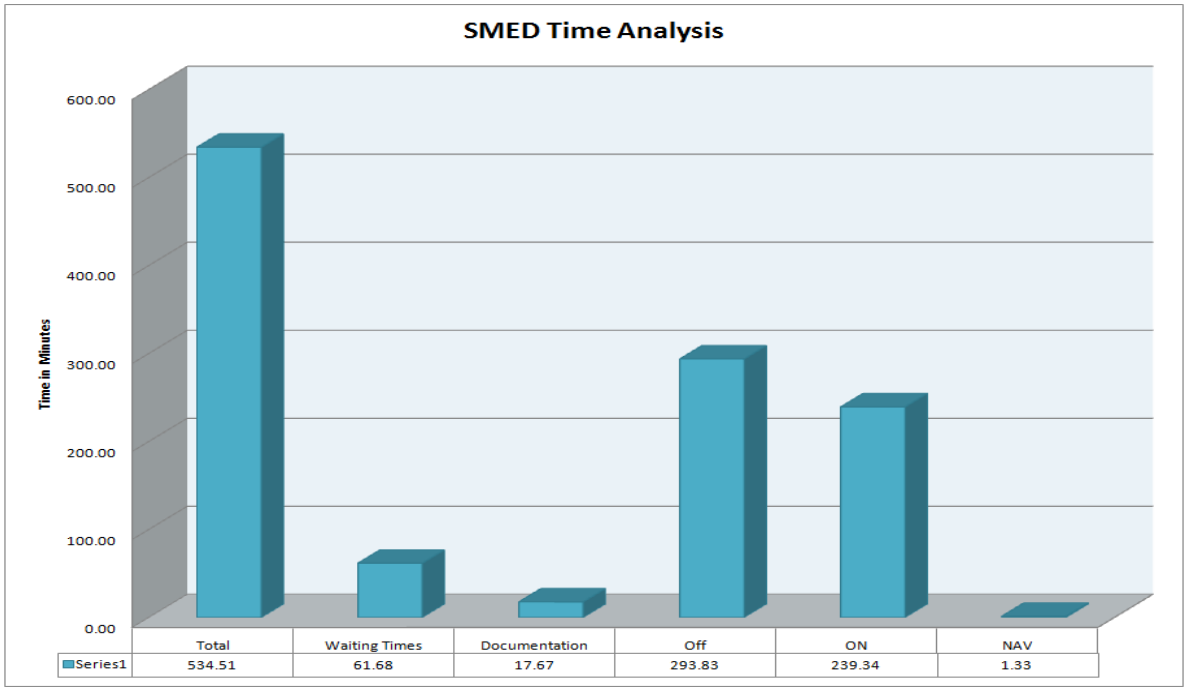


Figure 9 shows the distribution of all the time collected in the SMED analysis.

The following list, are the new equipments and materials bought to improve the process:

- Flashlight
- New platform

IMPROVEMENTS

Filter Change

New SOP

This method of twist and cut is new for the operator and the mechanics. One way to reduce the learning time was developing a new SOP with visual aid to help them understand the process quicker.

Equipment and Materials

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 10 and 11 describe the cost of the filter change, before and after improvements.

- New cutting tool
- Bag dispenser
- Thinner bag

Filter Change Material and Labor Cost				
Item name	Unit Price	Quantities 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 9
Major Changeovers SMED Analysis Time Distribution

FIGURE 10
Filter Change Cost Before Improvements

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 11
Filter Change Cost After Improvements

One of the most significant improvements was the acquisition of a new platform with collapse capable guard. This new platform facilitates the filter change. The acquisition of this platform was trough a capital project. Image 3 shows the new platform and Image 4 shows a tool box used to store the new tools.

Image 3
New Platform to Facilitate the Filter Change

Image 4
New tools and 5S Tool Box

Frequency reduction

After analyzing the waste collected from the dust collectors and the used filters, the frequency of the filters change was changed from 100 hours of coaters run time to 160 hours, this because not one of the discharges exceeds the 25 kg permitted by an ergonomic safety requirement. No further frequency reductions were pursued because poor filters condition can affect performance. Table 2 shows the waste analysis summary and Table 3 shows the frequency reduction.

Table 2
Waste Analysis Summary

Waste Analisys Summary			
Bay	Hours of Use	Average Filter Weight	Discharge Weight
1	170.3667	6.5125	15.3
4	152.9833	7.5125	10.6
1	171.85	6.05	24
4	175.3	6.025	23.2
2	166.15	7.43	12.6

Table 3
Filter Change Frequency Reduction Per Year

Frequency reduction per year	
Filter change requires per year if change every 125 hrs.	68
Filter change requires per year if change every 160 hrs.	58
Total Reduction	10

Major Changeovers

SOP and Forms Revision Kaizen

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 5 shows the working team of the Kaizen, a representation of Quality, Safety and Manufacturing areas were present.

Image 5
SOP and Forms Revision Kaizen

Image 6
Standardize Work and Time Collection Table Placed in The Coating Room

Suspension Offline

De-foaming time (4hours) is necessary to start the coating application, to prevent air to enter in the application lines of the coaters. The current average times of the major changeover process are 6.5hours; 2 hours more than the target time of 4.5hours and the de-foaming time and suspension preparation contribution is approximate 20%. The preparation suspension was removed from the changeover and done during the coating process; this is done by moving the tank to another station in the suspension preparation room.

Standardize Work

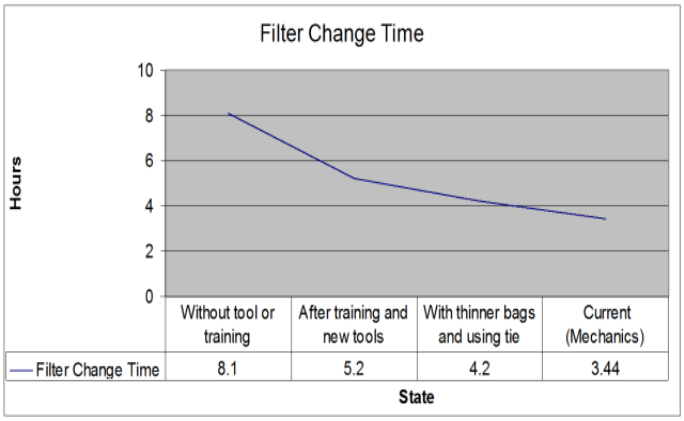
The most complicated, but most needed improvement is the changeover process standardization. A standardize work was developed after the SOP revision as a control method to minimize the opportunities to go back to the original state and minimize variability between operators. The work is divided in operators and machine time also is established. Image 6 shows the standardize work table and the time collection table placed in the coating room. In each of the major changeover, the operator follows this standard work and document the overall time.

CONCLUSIONS

Improvement Benefits

After the improvements were made, the process was transferred to the mechanic group. Their knowledge of the equipment's and flexibility helped reduce the time and increment the operator availability. The current filter change time performed by the mechanical group is 3.44 hours, as shown in Figure 12. This is a reduction of 57% compared to the original time. This filter change time is lower than a minor changeover (4.5 hours). For this reason, no impact in the production plan is expected.

FIGURE 12
Filter Change Performance



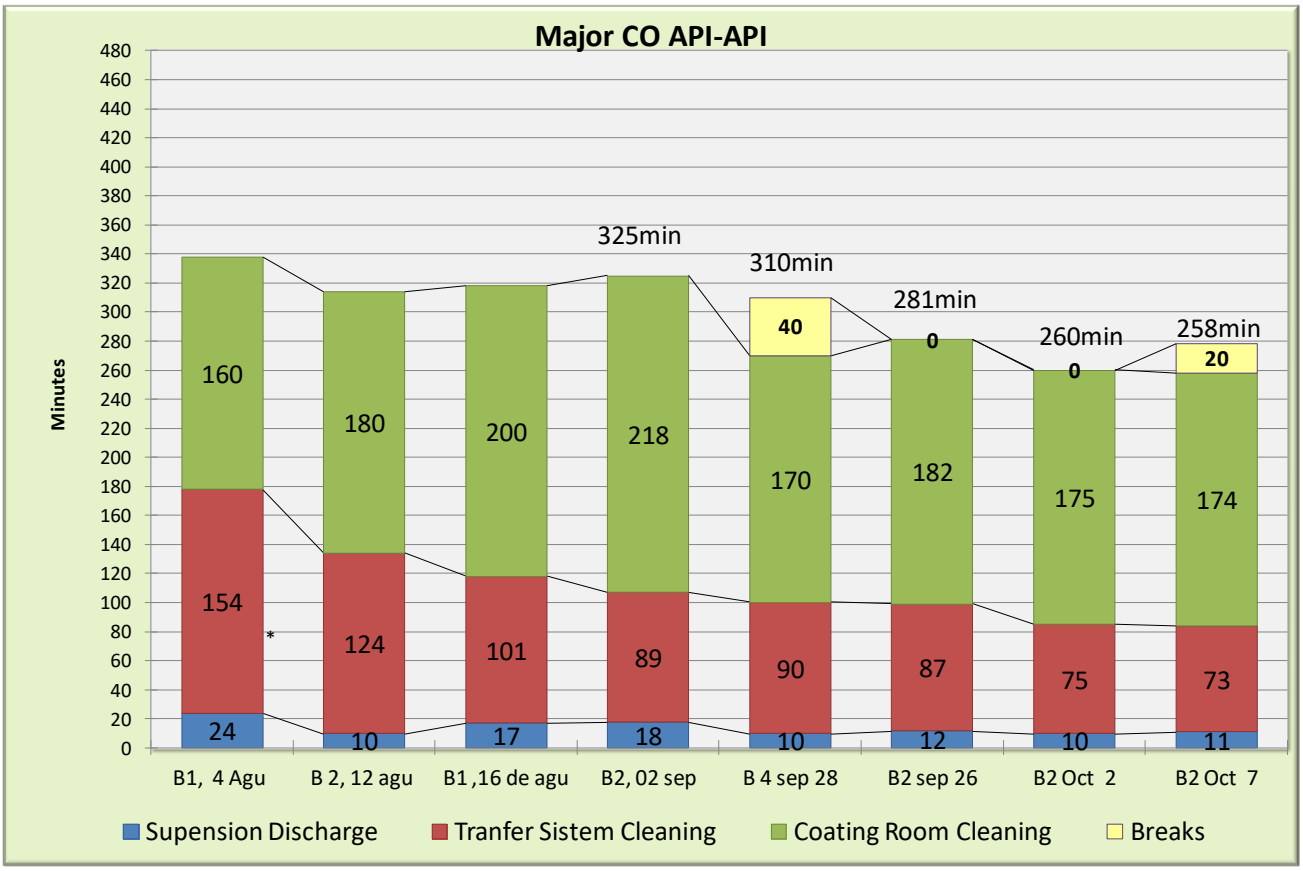
As for the major changeovers, after completing all the improvements and establishing the standardize

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
- Financial Benefit in labor cost of $31,574 per year

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.



Lesson Learn

After the completion of this project, it was learned that there are many opportunities in the production

References

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