Reduction of Time in a Manufacturing Process for a Pharmaceutical Company Located in Puerto Rico

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Abstract *— The project is developed in a chemical plant of a pharmaceutical company in Puerto Rico. In 2011 the company had an increase in market demand of the active ingredient of one product. To ensure the profit plan, it was necessary to increase the output from 5 to 6.5 batches/week of the active ingredient by reducing the time of the process. The project was developed by the use of the Lean Six Sigma Methodology. After the implementation of the project the financial benefit was a avoidance cost of approximated $810,000 during the manufacturing after the implementation of the project. The project exceeds the expectations of the proposed target with an average time reduction of 43% in the total time of the discharge. The variability was reduced by 69% of the standard deviation. At the end the company was able to supply de demand of 6.5 batches/ week of product.*

Key Terms *— DMAIC, Lean Six Sigma, Pharmaceutical, Standardize.*

INTRODUCTION

During April to May 2011, the discharges of the batch from the tank to the sack take an average of 5.4 hr with a standard deviation of 3.7 hr. These times don't let to increase the output of the batches per week and doesn't let enough time to compensate the production in case of maintenances and break downs. The objective of the project is to reduce from 5.4 hr to 3.5 hr the process time of the discharge and the standard deviation from 3.7 hr to 0.5 hr by the end of 2011.

The project is going to focus in the last step of the process in the last tank. This last step consists of the discharge of the content of the tank, a solid white powder, into sack of 400 kg. This step is one of the bottlenecks of the entire process of production of the active ingredient.

Project Contributions

Contributions by performing the project are:

- Increase in production – The increase in production help to reduce cost per batch making the process most cost effective.
- Time and Cost Reduction – The reduction on time of the process allow to increase the amount of batch per week of active ingredient and the product.

LITERATURE REVIEW

The literature review for this research was focused on the Lean Six Sigma methodology to be used and overview of the manufacturing processes required to produce the active ingredient.

Lean Six Sigma

Lean Six Sigma combine and complement the tools of both methodologies in a way to reduce waste and variations in the process.

Lean Manufacturing

Lean is a philosophy with a set of tools that assist in the identification and steady elimination of waste [1]. As waste is eliminated quality improves while production time and cost are reduced. The Lean philosophy work from the perspective of the customer who consumes a product or service. In other words this production practice considers the expenditure of resources for any goal other than the creation of value for the end customer; value is defined as any action or process that a customer would be willing to pay for.

Six Sigma

Six Sigma is a problem solving methodology than can be apply to any process to find and eliminate the root cause of the defect or problem.

The methodology focuses the attention in the elimination of the variation and defects of the process.

The Six Sigma methodology generally consists of five phases; Define, Measure, Analyze, Improve and Control know as DMAIC. The five phases can be used to identify and solve root causes of process problems, and to establish best practices to ensure that the solutions are permanent and can be replicated. DMAIC can be applied in complex problems in where causes and solutions are not obvious; also can be use in where the solution risks are high[2].

- Define – the objective of this step is to identify the problem, the scope of the project, sponsor of the project, resources needed, goals, business impact and project plan.
- Measure – the objective of this step is to evaluate and understand the current state of the process to establish a base line. The phase involves collecting data and developing a list of key process inputs variables (KPIV) and key process output variables (KPOV).
- Analyze – the objective of this step is the evaluation of the cause-and-effect relationships in the process and to understand the different sources of variability.
- Improve – the objective of this step is the development and implementation of solutions to the problem. Also pilot test and simulations can be done.
- Control – the objective of this step is to implement the final solutions and established the necessary controls to ensure that the gains from the project will be maintained and are adequate to the solution of the problem.

Active Ingredient Manufacturing Process Overview

The manufacturing process of the active ingredient consists of the use of 8 tanks as is illustrated in Figure 2. In each tank is conducting a series of steps and chemical reactions to carry out the manufacturing process. The project will be conducted in the last tank. At these tank is performed a series of steps in order to finish the final product. In general the first step in the tank is a filtration, the second step is a drying and third and last step is the discharge of the product in to the sack (FIBC) in this third step is in where the efforts will be concentrated. This step is making by the operators in the field by operating the agitator of the tank and the filler (PK). All these steps are make by manual operation of the agitator the filler and the sacks[3][4].

In the discharge step the mayor operation is the use of the agitator by the operator to discharge the product in to the sacks. An illustration of the equipment is presented in Figure 1. The manipulation of the agitator consists in up and down the agitator and the velocity or RPM of the revolutions of the agitator. Also include the skills and the judgment of the operator in interpretation of the automatic signals and observations of the product to make the discharge[3][4].

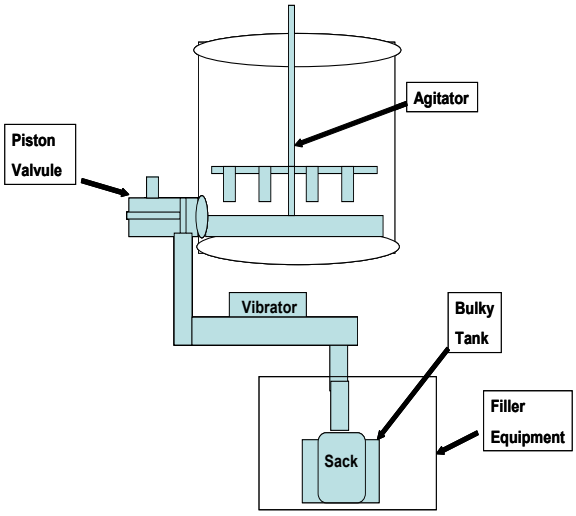

Figure 1
Equipment Illustration

In the discharge step the mayor operation is the use of the agitator by the operator to discharge the product in to the sacks. An illustration of the equipment is presented in Figure 1. The manipulation of the agitator consists in up and down the agitator and the velocity or RPM of the revolutions of the agitator. Also include the skills

and the judgment of the operator in interpretation of the automatic signals and observations of the product to make the discharge[3][4].

METHODOLOGY

Lean Six Sigma techniques were used in the development of this project. In special the DMAIC methodology was used for this Project. Information of the Define and Measure phases are described below.

Define

During this phase the project charter is define by identifying[2]:

- Business Case
- Problem Statement
- Goal Statement
- Sponsors
- Project Scope
- Recourses
- Project plan
- Expected benefits
- Voice of Client
- SIPOC
- Observations of the process
- High level process Map

Measure

During this phase the following activities will be performed:

- Data Collection Plan
- Measurement System Analysis
- Collection of the historical data from Batch Records
- Base line and Process Capability
- Detailed Flow Process Map
- Value stream map

Analyze

Through this phase a root cause investigation will be performed during a workshop with an interdisciplinary team from the process data, test results data collected and observations. The following tools will be used during the root cause investigation:

- Fish Bone of Possible Causes
- Root Cause Identification
- Possible Solutions
- Control Charts
- ANOVA
- Tow Sample T-test

Improve

During this phase an effort and impact prioritization matrix was use to choose the best solution. Also was developing an action plan and a communication plan from the chosen solutions. In addition in this phase was implemented some of the solutions[1][2].

Control

In this phase was developed a control plan to assure the effectively of the solutions and compare the results with the base line and old analysis from the analysis phase[1][2].

RESULTS AND DISCUSSION

The investigation findings and outcomes will be presented in this section, as well as, the discussion of them.

Define

The define is the most important and extensive phase. This phase was develop with several subparts as follow:

- **Project charter:**
  - **Business Case:** In 2011 the company had an increase in market demand of this product. To ensure the profit plan, it was necessary to increase the output from 5 to 6 batches per week of the active ingredient by reducing the time of the process.
  - **Problem Statement:** During April to May 2011, the discharges of the batch from the tank to the sack take an average of 5.4 hr with a standard deviation of 3.7 hr. These times don't let to increase the output of the

batches per week and doesn't let enough time to compensate the production in case of maintenances and break downs.

- **Goal Statement:** The objective of the project is to reduce from 5.4 hr to 3.5 hr the total time and from 3.7 hr to 0.5 hr the standard deviation of the discharge of the batch to the sacks by the end of the year 2011.
- **Sponsors:** Production management.
- **Project Scope:** The project is going to focus in the last step of the process in the last tank. This last step consists of the discharge of the content of the tank, a solid white powder, into sack of 400 kg.
- **Recourses:** To perform the project was needed personal from different areas of the project. This ensure the success of the project by providing the knowledge, resources and experiences need. Some of this personal are chemical operators, supervisors, Process Engineer, Safety representative, Global technical operation representative, Process expert, environmental representative, Quality representative and the project leader.
- **Project plan:** The project is going to be performed by the following phases and date (Table 1).

Table 1
Phase Dates

Task/Phase	Start Date	End Date
Define	1-June-11	8-june-11
Measure	9-June-11	13-june-11
Analyze	15-june-11	15-July-11
Improve	18-July-11	12-Aug-11
Control	15-Aug-11	23-Sep-11

- **Expected benefits:** In the development of this project the followings benefits are expected:
  - Increase in production – The increase in production help to reduce cost per batch making the process most cost effective.
  - Time and Cost Reduction – The reduction on time of the process allow increasing the amount of batch per week of active ingredient and the product.
  - $810,052 for the last 16 weeks of the year.

- **Voice of Client:** The voice of the client (Table 2) was performed by interviews to all level of management of the area in order to understand and recollect their expectations and worries about the project impact on the area.

Table 2
Voice of Client Table

Clients' Needs	Critical to Satisfaction	Metric
Reduction in Unload Time	Discharge time reduction	Average Time 3.5 hrs
Reduction in Time Variability	Reduction in Time and Standardization of Operators Behaviors	Standard Deviation ±0.5 hrs
Zero compliance/atypical due to any initiative implemented in the project.	No increase of atypical (due to project initiatives)	Number of atypicals =0(due to project initiatives)
Any initiative shouldn't impact environment.	No increase of environmental incidents (due to project initiatives)	Number of environmental incidents = 0(due to project initiatives)
Any initiative shouldn't impact safety.	No increase of safety incidents (due to project initiatives)	Number of safety incidents = 0(due to project initiatives)

- **High level process Map:** In order to have a general vision of the process and the importance of the steps of interests a High level process map was generated and presented in Figure 2.

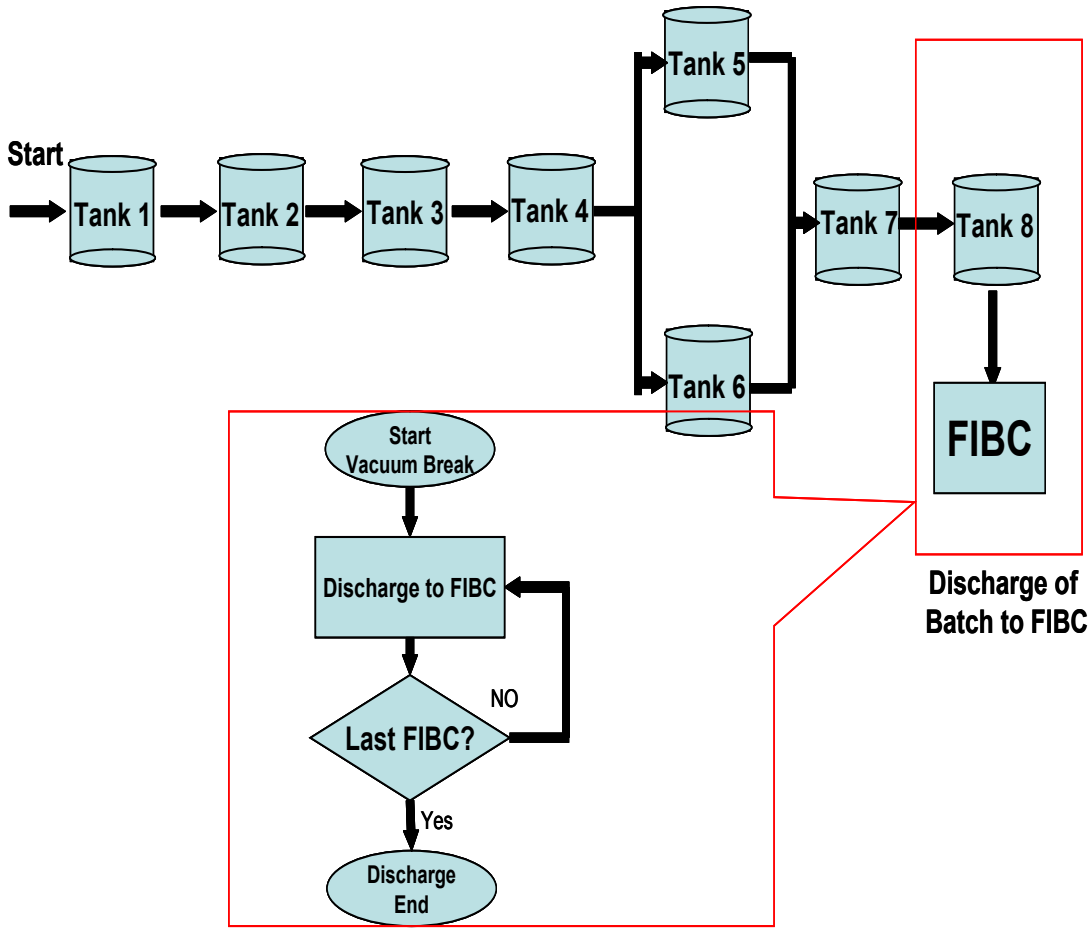

Figure 2
High Level Flow Diagram

- **SIPOC:** To have a better understanding of the process a SIPOC was created. This kind of diagram helps identifying the outputs, inputs, suppliers, customers and some critical steps of process. Also the SIPOC help to focus where the process could be improve[3].

Measure

During this phase the following activities was performed:

- **Data Collection Plan:** As part of the project during the measure phase a data collection plan was developed to thoroughly understand the process current state and collect reliable data. Data was used to expose the causes of problems. The Data Collection Plan will clarify the data collection goals and determine what, where, when, by who, and how many data will be collected. Also a data collection plan was developed a presented in Table 3.

Table 3
Data Collection Plan

Measure (Output)	Operational Definition	Where will the data be obtained?	How will the data be collected?	Who will be collecting the data?	When will the data be collected?	How much will be collected?
Discharge time (hr)	When brake vacuum in the drying process to the first step in Blow the PDV.	Data will be obtained from the batch sheets	Hours and date are obtained from the batch records and time is calculated.	Julio E. Cruz	Historical Data from April 2011 to May 2011.	At lest 30 Batch from April 2011 to May 2011
How will the data be used?			**How will the data be displayed?**			
Determine Baseline Process capability Process control			Summary Chart Process Capability Chart Control Chart			

- **Measurement System Analysis:** Manual data collection system was developed by using the batch sheet record to calculate the discharge and packaging time. The system records the time stamp of certain steps of the process used to make the time calculations. The data collection process time could include any downtime during the process steps execution. The baseline data was collected by me.

  In order to demonstrate the Measurement System data entry accuracy, 2 people verify the start and end time of 25% of the batches recorded in the batch record. (Table 3)

  Data collected:

  13 Batch start and end time used to calculate the time.

  Sample size: 91 entries

  Errors founded: 1 entry

  Accuracy = (91-1)/91)*100 = 98.9%

- **Base line and Process Capability:** In the summary of the statistics presented in Figure 3 we can observe a mean of 5.39 hrs and a standard deviation of 3.67 hrs. This result is far from the target established in our goal statement.

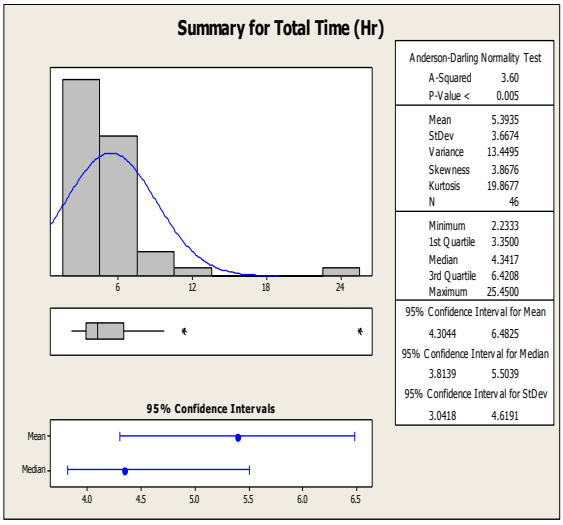

Figure 3
Statistic Summary

The process is operating in presence of special causes, making the process out of control. By carefull observation of Figure 4 we can see that the process is far from the target established in our goal statement.

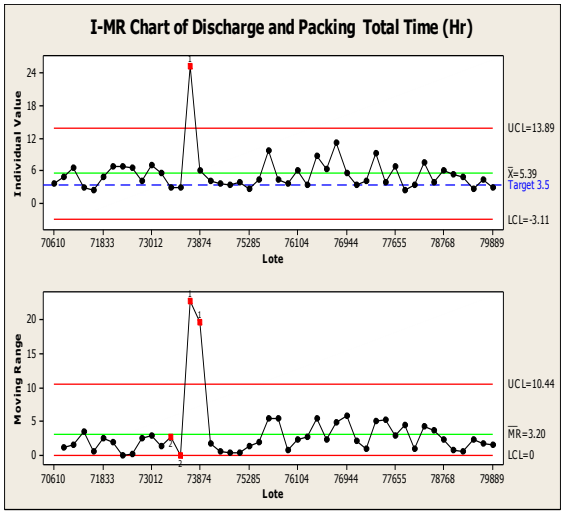

Figure 4
Discharge and Packing Total Time Baseline

At the moment the process is not able to reach our target. The variability has to be reduced, the mean of the process and all of the right part of the graphic has to be shifted to the left. The 56.82 % of the data is higher than of the upper limit of the process. To access process capability special causes were eliminated from the data and the control chart the results are showing in the Figure 5.

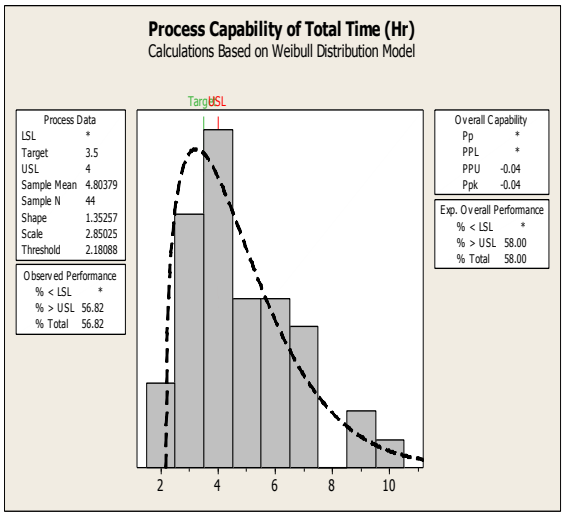

Figure 5
Process Capability

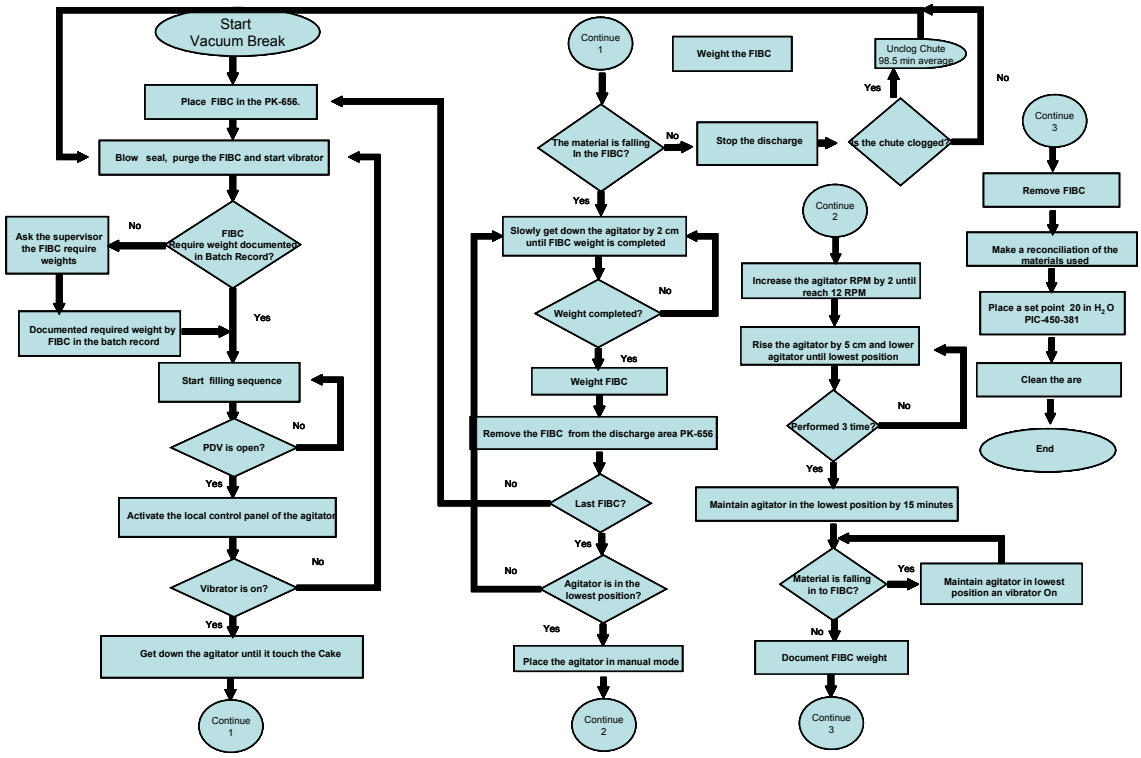

Figure 6
Process Flow Methodology

- **Detailed Flow Process Map:** A detailed Flow Process Map from the discharge was created in order to understand the process made by the operators to identify areas of opportunity. Whit this process flow we want to exanimate the process methodology and find and identify the practices of the operators vs. the writhing procedures. All the process is presented in Figure 6.
- **Value stream map:** A value stream map was created to study and evaluate the discharge process. In the value stream map (Figure 7) we divided the process mayor steps and determinate the average times for each steps.

Analyze

During this phase a root cause analysis will be performed during a workshop with the help of an interdisciplinary team. In the analyze phase was use different tools to identify problems affecting the key input and output variables. By a carefully analysis possible causes are studied to be classified, narrowed down and prioritized. Also root cause and solutions to these possible causes are determined in this phase to mitigate problems.

Opportunities were classified as they are related to methods, machine, equipment, documentation, people, and materials (Figure 8 and Table 8).

An affinity diagram was used to reclassify and narrow down the causes to packaging line specific needs. After performing the affinity, 15 possible causes were acknowledged. A prioritization matrix in terms of impact and effort were classified and ordered to develop an action plan that will mitigate problems root causes. During the workshop 20 possible causes were identify. A 5 why's analysis (Table 4) was performed to identify each root cause. The results are presented in the Table 4.

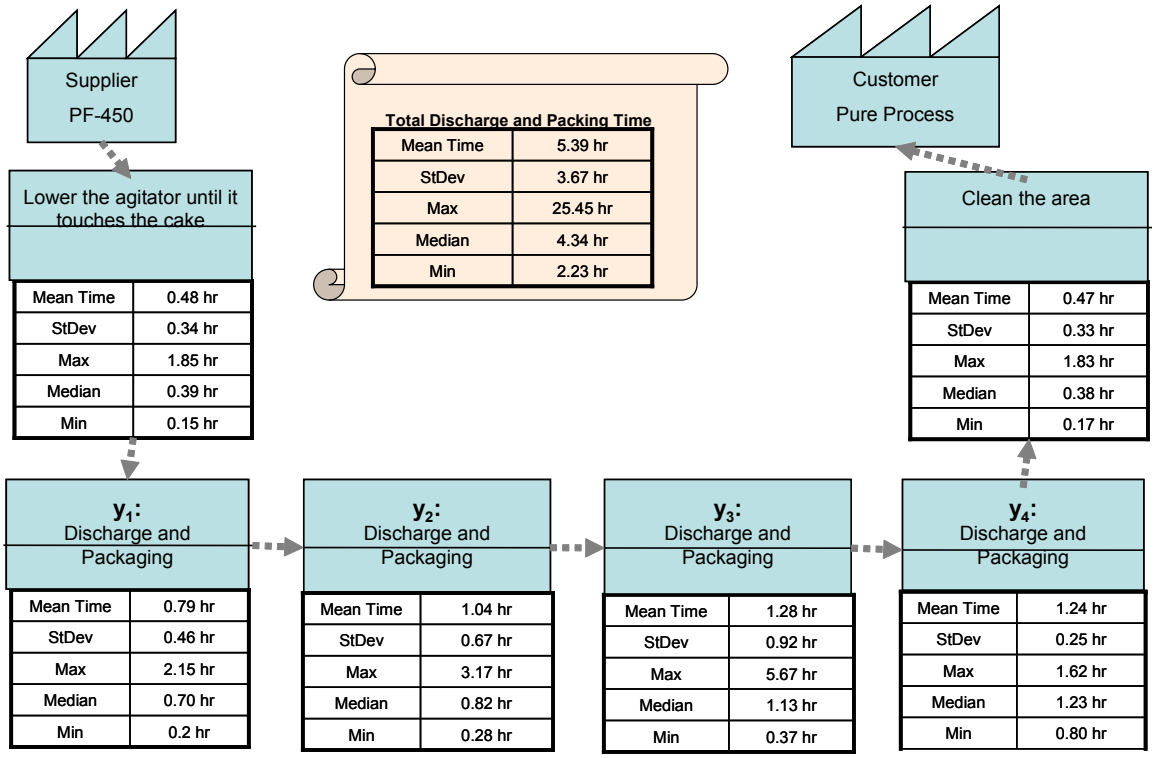

Figure 7
Value Stream Map

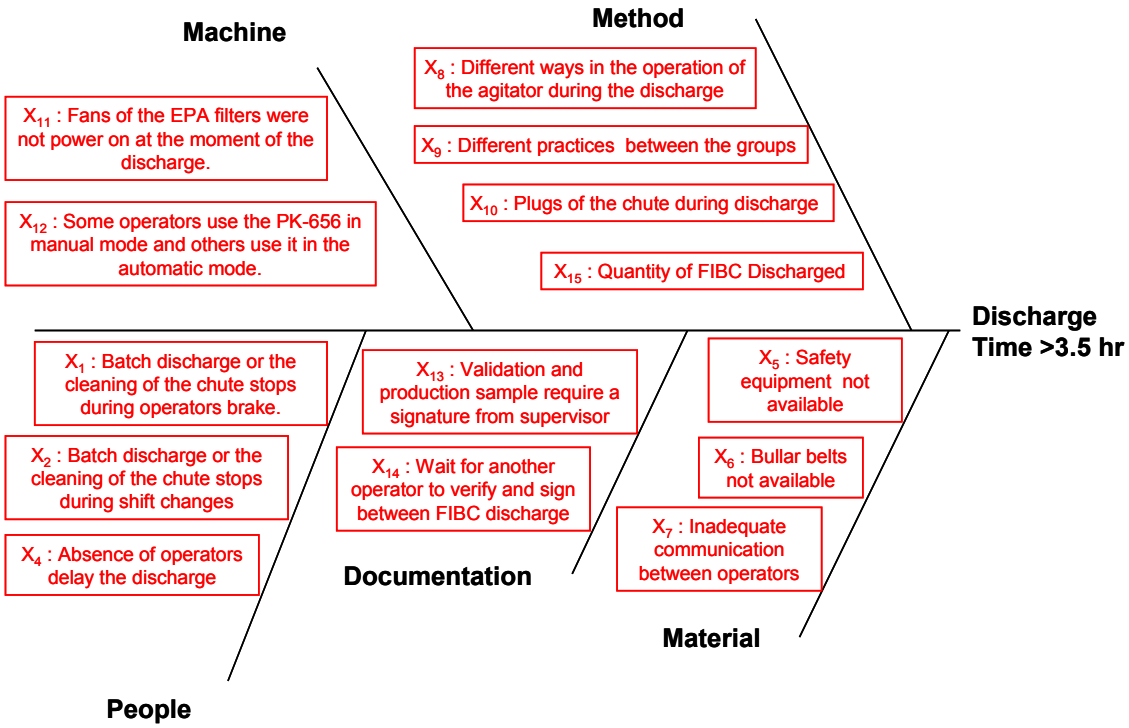

Figure 8
Fish Bone of Possible Causes

Table 4
Root Cause Identification

Category	Possible cause	Root Cause
People	Batch discharge or the cleaning of the chute stops during operators brake.	Break must be taken between the third and fifth hour of the shift and there is no available operator to substitute the one in break.
People	Batch discharge or the cleaning of the chute stops during shift changes.	The operators stop the discharge or the cleaning of the chute during shift changes because they are not aware of the impact on the final output at the end of the week.
People	Area not prepare at the moment of the discharge	The area is not prepared before the discharged due to a lack of operators with forklift driver license.
People	The absences of operators delay the discharge.	There is no available operator to substitute the absent operator.
Material	Safety equipment not available	There is no instruction and responsible person or resource to fill in and keep organized the cabinet of PPE.
Material	Bullar belts not available	Bullar belts are not available because they were broken or lost.
Material	Inadequate communication between operators	Communication between operators is ineffective due to lack of radio because there are many in reparation
Method	Different ways in the operation of the agitator during the discharge	The operator lowers the agitator using their judgment and experience because the instructions of the batch sheet are not entirely clear and detailed.
Method	Different practices between the groups	The instructions in the Batch sheets are not entirely clear and they are very general. They also need to be checked against the current operation practice.
Method	Plugs of the chute during discharge	The step to rise and lower the agitator is not standardizing.
Machine	Fans of the EPA filters were not power on at the moment of the discharge	Operators do not check the fans because instructions to verify them are not in the batch sheet.
Documentation	Validation and production sample require signature from supervisor	The discharge is interrupted by waiting for the signature of the instruction to take the sample of validation and final product.
Documentation	Wait for another operator to verify and sign between FIBC discharge	Waiting time too long because the absence of operators or operators lunch break

As part of the analysis of the process and using the historical data and the data collected during the field observations we check if there exists any difference in the total time of the different groups of operators. To make the analysis a One Way ANOVA test was used (Figure 9). All assumptions of normality and equal variances were meeting.

```
Source  DF      SS     MS      F      P
Grupo    3  22.817  7.606  12.38  0.000
Error   17  10.442  0.614
Total   20  33.259

S = 0.7837   R-Sq = 68.60%   R-Sq(adj) = 63.06%

                          Individual 95% CIs For Mean Based on
                          Pooled StDev
Level  N    Mean   StDev  ---------+---------+---------+---------+
A      7  2.2352  0.2783  (---*---)
B      3  5.4767  1.3844                    (------*-----)
C      7  3.2590  0.7150         (---*---)
D      4  3.7075  1.0127          (-----*----)
                          ---------+---------+---------+---------+
                                 3.0       4.5       6.0       7.5

Pooled StDev = 0.7837
```

Figure 9
One way ANOVA Test Print Out

ANOVA Test

H0 : $\mu a = \mu b = \mu c = \mu d$

H1 : At least one of the means is different

P-Value = $0.00 \leq 0.05$

Therefore at least one of the groups is different.

There is a statistical difference of at least one of the groups. It can be observe in the graphic and the statistics that group A has the best performance as observed in Figure 9. By standardizing the best practices the group's performance could be equalized.

Also as part of the analysis of the process we want to know if there exists any difference in the total time of the discharge of Automatic vs. Manual mode (Figure 10). To make the analysis a 2 sample t-test was used. All assumptions of normality and equal variances were met.

```
Two-sample T for Tiempo

Mode        N   Mean  StDev  SE Mean
Automatic  10  3.210  0.670     0.21
Manual     12   2.87   1.00     0.29


Difference = mu (Automatic) - mu (Manual)
Estimate for difference:  0.336
95% CI for difference:  (-0.439, 1.111)
T-Test of difference = 0 (vs not =): T-Value = 0.91
 P-Value = 0.376  DF = 20
Both use Pooled StDev = 0.8676
```

Figure 10
2 Sample t- Test Print Out

2 sample t-test

H0 : μAuto = μManual

H1 : μAuto ≠ μManual

P-Value = 0.376 ≥ 0.05

Therefore μAuto = μManual

There is not a statistical significant difference in the discharge time between Automatic vs. Manual Mode.

As well as part of the analysis of the process we want to compare and know if there exists any difference in the total time of the discharge of 3 vs. 4 FIBC (Figure 11). To make the analysis a 2 sample t-test was used. All assumptions of normality and equal variances were met.

Two-Sample T-Test and CI: Tiempo, Numero de FIBC

```
Two-sample T for Tiempo

Numero
de FIBC   N   Mean  StDev  SE Mean
3        14  3.035  0.932     0.25
4         8  3.012  0.792     0.28


Difference = mu (3) - mu (4)
Estimate for difference:  0.023
95% CI for difference:  (-0.772, 0.817)
T-Test of difference = 0 (vs not =): T-Value = 0.06
 P-Value = 0.952  DF = 16
```

Figure 11
2 Sampl t- Test Print Out

2 sample t-test

H0 : μ3 FIBC = μ4 FIBC

H1 : μ3 FIBC ≠ μ4 FIBC

P-Value = 0.95 ≥ 0.05

Therefore μ3 FIBC = μ4 FIBC

There is not a statistical significant difference in the discharge time due to the FIBC quantity.

Improve

In the improve phase all actions selected as potential solutions in the Analyze phase were developed. During this phase an effort and impact prioritization matrix was used to choose the best solution. The estimated total time benefit after the prioritization is about 170 min (2.8 hr). The action plan and the prioritization are presented in the Table 5 and Table 6. The items in green are the one chosen for do it. The red ones are for reconsideration and there are not going to be pursued at the moment because they represent to much effort.

Table 5
Possible solutions and Prioritization

Possible Solution	Benefit	Effort	Impact	Priority
Create awareness of the impact of the amount of lost time vs. the new plan of production to assure a good coordination of lunch breaks.	40 min	L	H	P1
Create a floating operator.		H	H	P5
Create awareness of the impact of the amount of loss of time vs. the new plan of production to assure a quick and efficient shift change	20 min	L	M	P2
Evaluate the distribution of operators with permit to operate forklifts per shift to reinforce the shifts that do not have sufficient licensed operators.	15 min	L	H	P1
Create awareness and methodology to assure 2 operators with forklift license in every group.		L	H	P1
Create a floating operator.	15 min	H	H	P5
6S event in the PPE cabinet of the area	15 min	L	M	P2

Give to each supervisor 2 bullars belt	15 min	L	M	P2
Provide a radio to each operator	10 min	M	H	P3

Table 6
Possible solutions and Prioritization

Possible Solution	Benefit	Effort	Impact	Priority
Standardize the practices of the operators during the discharge process and develop and include the use of the inches of water of the signal PIC-450-381	30 min	L	H	P1
Make an evaluation of the batch sheet instructions and standardize the practices of the operators during the discharge process		L	H	P1
Standardize the practices of the operators during the discharge process and develop and include the use of the inches of water of the signal PIC-450-381		L	H	P1
Place instructions or note in the batch sheet	15 min	L	M	P2
Place visual signal on the first floor to indicate the status of the fans and put a switch to turn on or off the fans.	15 min	H	M	P6
Move step 31st (samples required for validation) at the beginning of the batch sheet and remove the box required or not required of the sample of the final product because this sample is always taken	10 min	L	M	P2
Create a floating operator	15 min	H	M	P6

Also an action plan (Table 7) and a communication plan from the chosen solutions was developed. In addition in this phase we implement some of the solutions.

Table 7
Action Plan

Potential Solution	Estimated Time Benefit	Priority
Create awareness of the impact of the amount of lost time vs. the new plan of production to assure a good coordination of lunch break.	40 min	P1
Create awareness of the impact of the amount of loss of time vs. the new plan of production to assure a quick and efficient shift change	20 min	P2
Evaluate the distribution of operators with permit to operate forklifts per shift to reinforce the shifts that do not have sufficient licensed operators.	15 min	P1
Create awareness and methodology to assure 2 operators with forklift license in every group 6S event in the PPE cabinet of the area	15 min	P1 P2
Give to each supervisor 2 bullars belt	15 min	P2
Provide a radio to each operator.	10 min	P3
Standardize the practices of the operators during the discharge process and develop and include the use of the inches of water of the signal PIC-450-381		P1
Make an evaluation of the batch sheet instructions and standardize the practices of the operators during the discharge process	30 min	P1
Standardize the practices of the operators during the discharge process and develop and include the use of the inches of water of the signal PIC-450-381		P1
Place instructions or note in the batch sheet	15 min	P2
Eliminate step 33 (samples required for validation)	10 min	P2

A communication plan (Table 8) was developed during the period of the project. In this communication plan was established the form, the way and the target of the introduction of many of the solutions presented in the action plan. Many of these solutions were introduce by training and changes in the batch sheet instructions focuses to the operators.

Table 8
Communication Plan

Objective	Key Messages	Target Audiences	Media
Action X1			

Reduction of time waste because of bad coordination lunch break.	Create awareness of the impact of the amount of lost time vs. the new plan of production to assure a good coordination of lunch break.	Operators	Individual meeting with the different operators group
Action X2			
Reduction of time waste during the shift changes.	Create awareness of the impact of the amount of loss of time vs. the new plan of production to assure a quick and efficient shift change	Operators	Individual meeting with the different operators group
Action X3			
Avoid waste of time because the area was not prepared.	Create awareness to assure 2 operators with forklift license in every group	Process Expert	Individual meeting with the Process Expert
Action X8, X9, X10			
Standardize the practices of the operators during the discharge process.	Standardize the best practices of the operators and develop and include the use of the inches of water of the signal PIC-450-381	Operators	Individual meeting with the different operators group, the inclusion of the practices in the Batch sheet and training

Control

In this phase we develop a control plan to assure the effectively of the solutions and compare the results with the base line and old analysis from the analysis and measure phase.

After the implementation of the standardization, 5-S event and many others solutions of the action plan we can be concluded that the standardization was accomplished because the performance of the groups are similar. In addition, all groups have a discharge time with an average below the target of 3.5 hr.

```
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                          ---------+---------+---------+---------+
                                 3.0       4.5       6.0       7.5

Pooled StDev = 0.7837
```

Figure 12
2 One-Way Anova Test Print Out Before Implementation

In the One Anova Test Before presentation presented above in Figure 12 the results was P-Value = $0.00 \leq 0.05$ meaning that at least one group is different. In the In the One Anova Test After presentation presented below in Figure 13 the results was P-Value = $0.317 \geq 0.05$ meaning that all groups are similar whit out any significance difference.

One-way ANOVA: Total Time (Hr) versus Group

```
Source  DF      SS     MS     F      P
Group    3   2.375  0.792  1.21  0.317
Error   44  28.767  0.654
Total   47  31.142

S = 0.8086   R-Sq = 7.63%   R-Sq(adj) = 1.33%

                          Individual 95% CIs For Mean Based on
                          Pooled StDev
Level   N    Mean   StDev  ------+---------+---------+---------+---
A      13  2.6154  0.9772  (----------*----------)
B      13  3.0654  0.5202            (----------*----------)
C      12  2.8181  0.8793       (----------*----------)
D      10  3.1983  0.7856              (------------*------------)
                          ------+---------+---------+---------+---
                             2.40      2.80      3.20      3.60

Pooled StDev = 0.8086
```

Figure 13
2 One-Way Anova Test Print Out After Implementation

After the implementation using a control chart we can observe the average time fall under the expected target of 3.5 hr to 3.06 hr, the variation of the process was reduced by 69% and the special causes were reduces too (Figure 14).

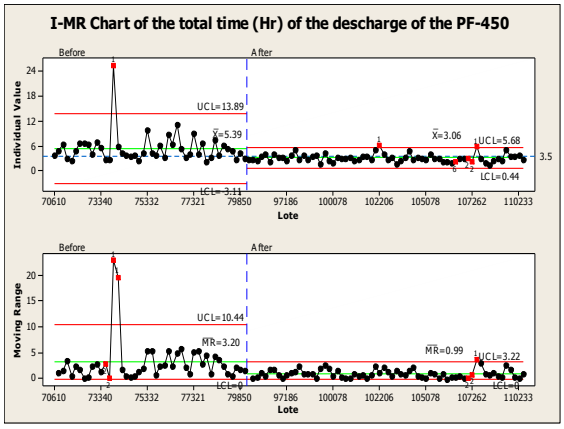

Figure 14
Control Chart

The estimated Financial Benefit after the implementation is around $810K for approximated 4 months.

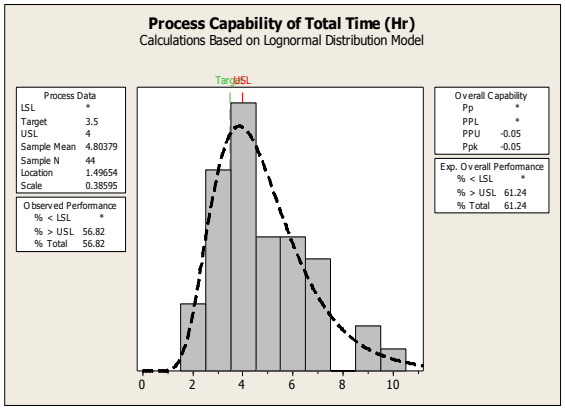

Figure 15
Process Capability After

After the implementation the capability of the process improve but still 12.12 % of the data is greater than the upper specification limit, indicating that continuous improvement should be pursue. In addition, the process mean fall under the expected target of 3.5 hr shifting the process mean to the left as required (Figure 15).

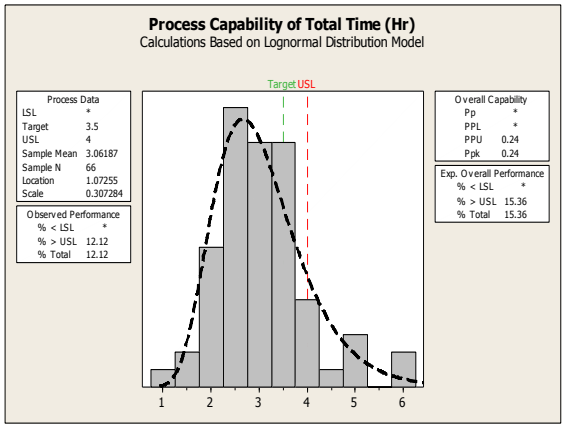

Figure 16
Process Capability Before

Once a carefully study of the Figure 16 and Graphic 5 we can observe an Ppk improved from -0.05 to 0.24. % and defects were reduced from 61.24% to 15.36%.

Also when we check our critical to satisfaction final results Table 9 we can find that all clients needs were meted.

Table 9
Voice of Client Final Results

Clients' Needs	Critical to Satisfaction	Metric	Results
Reduction in Unload Time	Discharge time reduction	Average Time =3.5 hrs	The expected target was exceeded Average Time = 3.06 hrs
Reduction in Time Variability	Reduction in Time and Standardization of Operators Behaviors	Standard Deviation ±0.5 hrs	Standard Deviation was reduced from 3.67 hr to .97 hr
Zero compliance/atypical due to any initiative implemented in the project.	No increase of atypical (due to project initiatives)	Number of atypicals = 0(due to project initiatives)	Number of atypicals =0
Any initiative shouldn't impact environment.	No increase of environmental incidents (due to project initiatives)	Number of environmental incidents = 0(due to project initiatives)	Number of environmental incidents =0

Any initiative shouldn't impact safety.	No increase of safety incidents (due to project initiatives)	Number of safety incidents = 0(due to project initiatives)	Number of safety incidents =0

CONCLUSION AND RECOMMENDATION

Based on the results of the actions implemented for the project improvement phase it can be concluded that the packaging line output consistently achieve an average time of 3.03 hr. The improvement of the process exceeded the expectations of the proposed target of 3.5 hr. This average time demonstrate a reduction of 43% in the total time of the discharge. The variability was reduced by 69 % from a standard deviation of 3.67 hr to .99 hr.

The company will be able to supply de demand of 6.5 batches per week of the product. This will contribute for a financial benefit of $810,000. Crews are going to be able to complete the weekly output targets from Monday to Sunday with enough spear time to do maintenances. The investment was minimums and the benefits in process efficiency are notable. Also all critical to satisfaction goals in the client needs of Table 9 were met.

REFERENCES

[1] Michael L. George, David Rowlands, Mark Price, John Maxey, *"The Lean Six Sigma Pocket Tool Book"*, *McGraw-Hill, Copyright 2005 by George Group.*

[2] Greg Brue, Rod Howes, *"The McDraw-Hill 36-hour Course Six Sigma", McGraw-Hill, Copyright 2006 by Greg Brue and Rod Howes.*

[3] Pharmaceutical Company Internal Manufacturing Process Documentation, *Process Fit*

[4] Pharmaceutical Company Internal Manufacturing Process Documentation, *Batch sheet*