Design Methodology of Clean Room Overtime Reduction in a Medical Device Plant

Yaxaira E. Pabellón Díaz
Master of Engineering in Manufacturing Engineering
Rafael Nieves, PharmD.
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract*— *According to the last year data in a medical device company, the packaging shipped units are increasing by the last eight months. The packaging clean room headcount are generate too much overtime affecting the finance metrics and the company goals. The manufacturing department is needed to extend the two existing shifts from 8 hours to 12 hours of daily work per 6 day at week, to meet with the production increasing the overtime in this work area especially the double time overtime (DTI).

Key Terms *— DTI, Medical Device, Packaging Clean Room, Production Increasing.*

PROJECT STATEMENT

The company is spending over $1 Million dollars in overtime. The company needs to do an arrangement to resolve this overtime because this can create a human error by the employee because they are working too much, also the employees are on risk to do a mix with the lots that they are working.

Mix is considered when two or more lots are involved in a label or package confusion. For example one lot can take the label of another lot with all the wrong specifications. This error can be capture in the final pack area or in the distribution center, this is considered an escape. Otherwise if the wrong product will be installed in a human body, or if the doctor noticed that the piece is not with the correct specifications (length, color, etc.), this is considered a field error.

The overtime reduction should be help in this practice; also the employees will be more rested. Quality of the product should be better in general.

RESEARCH DESCRIPTION

This project consists in a methodology creation to know how much is the overtime percent generate in the packaging clean room per shift and how much this overtime cost to the company. This will provide to the company a saving in the annual finance metric and to the packaging department. Also the company will be sure about the efficiency of each employee, and the product quality when they only work 8 hours per day.

RESEARCH OBJECTIVES

The objectives of this research work can be summarizes as:

- Measure how much is the overtime in the packaging clean room.
- Reduce by 16% the overtime in the packaging clean room area.
- Increase the employee efficiency working 8 hours per day.

RESEARCH CONTRIBUTIONS

With the implementation of this project, the packaging clean room department will reduce 16% of the overtime percent. The company will safe approximately $300K for this department. Incentive plan associate with overtime will be less and the employee efficiency will be better decreasing the working cycle from twelve to eight hours per day. The packaging team will exceed the expected goal (units shipped) because the rate of each shift should expect the minimum required. The life quality of each employee will be better; they can share with their families and/or friends. The company will have happy and engagement employees and their finance will be increasing by the time.

LITERATURE REVIEW

Medical Device Industry use their technology to alleviating pain, restoring health, and extending live, for the last 40 years in Puerto Rico this company is helping people to live with less or without pain in their bodies. The manufacturing and packaging process in some steps is mostly manual.

The packaging clean room has some steps for a screw package, the first step consist in a cleaning area, the screws can sterilize in alcohol 70/30% or 99%, then the next step is the sterile package here is when the operator pack the screw into a blister and the machine seal the blister with a lid. The third step is to put the blister into a carton and post the label, the final pack is to paste the carton by a machine that shrimp and seal the carton. The final pack process is completely manual. For the last year the company demand was increasing. The packaging clean room employees need to work 12 hours per day (per 2 shift) and 6 days per week. This is a concern to the company because the employees can make a production or quality error affecting the company metric.

Hundreds of companies around the world have adopted Six Sigma as a way of doing business [1]. Six Sigma was originated to improve manufacturing processes and eliminate defects. This methodology was originated by Bill Smith at Motorola in 1986, Six Sigma assets that continuous effort are of vital importance to the company success, manufacturing process have characteristics than can be measured, analyzed, improve and controlled and the last one is that the quality improvement need the commitment from the entire organization. Motorola engineers decide that the traditional quality levels didn't provide enough granularities [2]. Motorola create this new standard and create the methodology and need cultural change associate with it. Six Sigma helped Motorola realize powerful bottom-line results in their organization; in fact they document more than $16 Billion in savings as a result of the Six Sigma effort.

Six Sigma projects follow the DMAIC project methodologies composed of five phases. DMAIC is used for projects aimed at improving and existing manufacturing process [3]. The DMAIC five phases are the following:

- ***Define*** the problem, the voice of the customer and the project goals.
- ***Measure*** key aspects of the current process and collect relevant data.
- ***Analyze*** the data to investigate and verify cause effect relationships, need to be sure that all factors are considered.
- ***Improve*** or optimize the current process based upon the data analysis techniques.
- ***Control*** the future state process to ensure that any deviations from target are corrected before they results in defects. This phase need to prevent quality problems.

METHODOLOGY

To achieve with the objectives of this project, the methodology used will be the DMAIC that is a process improvement tool, this methodology is link to Six Sigma and consist of five phases define, measure, analyze, improve and control [4].

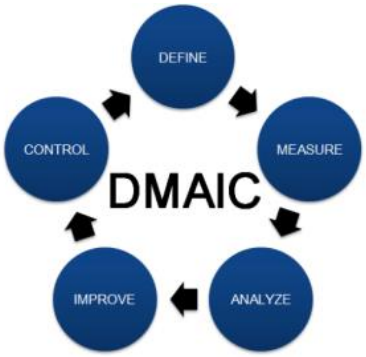

Figure 1
DMAIC Cycle

Define Phase

This phase is the confirmation that there is indicator of an issue. This step will consist of define the problem, what is the goal of the design project and what are the benefits, also it will determine what areas will be in the project scope.

It will be use a voice of customer (industry management) concern.

Measure Phase

This phase consist of determine the start point or baseline of the process and looking for clues to understand the root cause. It will generate a plan to determine how it will collect the data to understand the root cause (overtime) and to know how much is this root cause.

Analyze Phase

Analyze phase consist in determine the root cause(s) and the vital few x's, Y=f(x) relationship [5]. This phase will be explained with a Pareto and it will define the cause effect theory. Analyze also consist of what the project owner do, and what about the risk and inefficiencies.

Improve Phase

Improve phase consist of develop potential solutions, in this phase it will validate the potential improvement like the packaging clean room is under headcount or it will not have manufacturing materials. This phase consist in correct or re-evaluate potential solutions.

Control Phase

The control phase consist in a constant monitoring of the process performance, in this phase it will generate a weekly report that show the output per shift and the weekly overtime to be sure that the reduction is constant.

RESULTS AND DISCUSSION

This chapter present the problem analysis and improvement results using the Lean Six Sigma Methodology and DMAIC tool.

Define Phase Analysis

The manufacturing process demand is increasing during the last year. The sterile product service and demand are having an increasing with the existing products and also with the new product launches and transfers from other sites.

The clean room manufacturing department is the focus of this sterile product, the packed in this medical device company is for 2 product, plastic and screw. Both products are for spinal operation in humans.

Clean Room operation increase from 6,000 to 10,000 screws per week and in plastic from 2,000 to 3,000 units per week, specifically in plastic families depends the demand the department can increase the production from 3,000 to 5,000 units per week.

The project goal is to reduce the overtime 16% in clean room department by the increasing in their sterile production. The project scope includes data from May 2014 to February 2015, this overtime data include the Double time (DTI),1.5 overtime (OTI), Meal penalty (MEA) and double time by seven day of work (7^{th} Day DTI).

This project benefits the company by saving $300,000 dollars and increasing the employee productivity and Quality in the sterile product.

The project members include the clean room manufacturing supervisor and a Black Belt, Master Black Belt, Sr. Supervisor and Finance member as support team member.

The manufacturing supervisor role is to collect all the overtime data week by week from May 2014 to February 2015 and perform the analysis with the support of the other team members. All activities will be completed as part of the DMAIC measure phase. The goal of this analysis is to establish what opportunities we have in clean room area to increase the production, employee performance and the Quality and increase the overtime and the possible mix or escape.

Measure Phase

To identify relation between suppliers, input, process, output and customers a SIPOC diagram was created.

Process Flow:

- The process starts with the units treatment. Supply chain department create the orders to manufacturing department, establishing weekly priorities, this priorities was based on the client

needs. In this case the company manufactures spinal screw to alleviate pain.

- When the orders are started, manufacturing department prepare the kits with the screw sub-components and assembly the units.
- After the assembled was finished, the screws pass to clean room to sterilize, package and inspection.
- Then the units will send to shipping department to final destination.
- If one of these departments had any deficiencies, this will generate overtime.

The manufacturing supervisor selects all the overtime data in 2013 and 2014. The analyze was based on meals penalties, 7th day pay code, double pay code hours and time and a half pay code hours. The conclusion was for the fiscal year 2014 the company pays $600,000 in overtime.

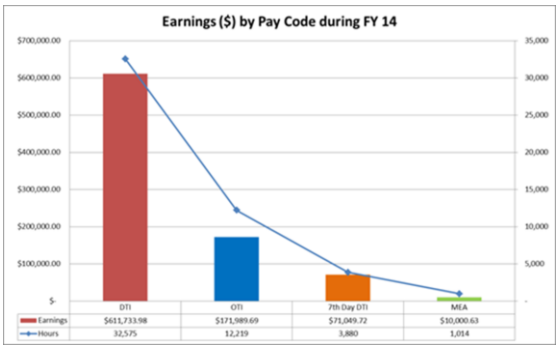

Figure 2
Earnings ($) Pay Code during FY14

Once the overtime in overall was discussed, the team members find by department where is this overtime generated. As part of their investigation the clean room department was highest department generate overtime hours, the total hours for the years 2013-2014 was 7,340, this overtime include the double time, the 7th day double time, meal penalty and 1.5 overtime. Now the team members can work with this overtime generate in clean room based on this graphic, implementing the results obtained in analyze phase.

The team members verified the data of the overtime by month. Depending the moth the clean room will need to work more overtime that other months, for example if is an end of one moth probably the clean room need to work overtime considering that the sterile product was send to sterilization before the final destination. Another factor to clean room can be the shutdown and the end of the fiscal year. The month with the most overtime generated was September with $30,483.

Headcount in clean room was the original theme speaking by the team members. The actual headcount was 34 employees, the required headcount was 38, the gap is 4 employees and the clean room losses 3 persons during this analyze, one person was fired and the other 2 was hiring in other manufacturing positions in another departments. After this analyzed the team members start to create cross matrix training to certify the 34 employees in more areas to reduce the overtime generate by absenteeism in this headcount.

Analyzed Phase

Analyzed phase is focused on the team reviews data collection plan to include additional information. The team members are focus in fiddling opportunities to reduce the overtime. The first step is to analyze the data collection, the department with higher overtime is clean room and this project is based in clean room manufacturing department. The second step is verify the opportunities area in the headcount gap the third step is identify how many training the employees have and how many more they need (cross training) to replace one employee by other and eliminate the overtime by absenteeism. The methodology used in this phase is a fishbone visualization tool that categorizes the potential causes of a problem order to identify its root causes.

After fishbone generation, the team members have the potential root causes in this analysis the team members will be focused on the top three reasons that impact overtime:

- Cross-Training
- New hire Training
- Lack of Personnel

Another very important factor to considering is that in February 2015 the clean room department

losses three (3) employees, that impacted the department in overtime for the next 2 months approximately.

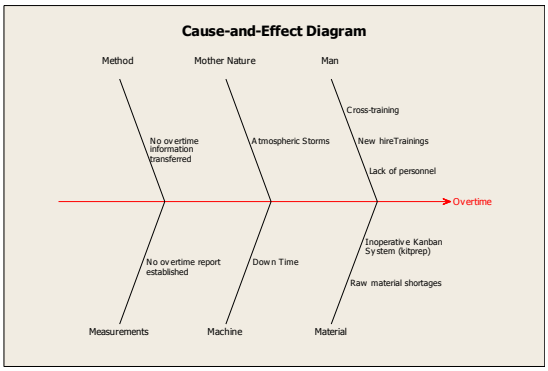

Figure 3
Fishbone Cause and Effect Analysis

The first opportunity area that team members have is the cross training plan, this strategy was created to certify experienced and new hire employees in different steps to compensate the absenteeism and the overtime. The table has an estimated complete date. The green employees already have their certifications, the yellow employees are in process to have the certification, and the pink employees are starting to take the training.

Improve Phase

After the team member analysis the company hired some employees for the clean room department to compensate the three (3) employees that were losses. These employees was certified in some areas, at the same time the experienced employees was certified in other areas to compensate absenteeism, on April 2015 the clean room do not have headcount GAP.

Table 1
Headcount 2015 Conditions

Headcount 2015 Conditions			
	September	**February**	**April**
Actual Headcount	**31**	**34**	**38**
Required Headcount	**38**	**38**	**38**
Gap	**7**	**4**	**0**
Losses	**1**	**3**	**1**

Otherwise the cross training was successfully completed by the team members. All the new and experienced employees had the different certifications in the clean room department.

As the team member when the cross training was done, the unit have more opportunities to rotate the employees in different.

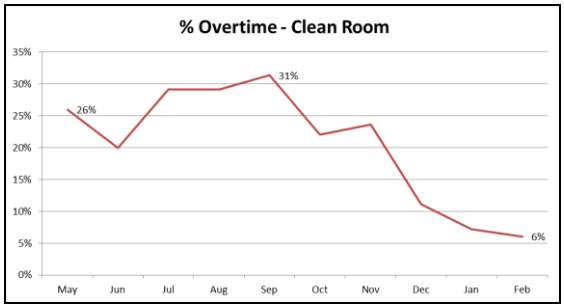

Figure 4
% Overtime – Clean Room

Control Phase

The primary objective of the DMAIC Control Phase is to ensure that gains obtained during Improve are maintained long after the project has ended [6]. To that end, it's necessary to standardized and all the employees have the same information.

During the improve phase the team members had implemented the cross training for the new and the experienced employees. The clean room department had a high absenteeism that was covered with the cross training. Before clean room department lose the three (3) employees, they trained another employees in their certifications, this plan was covered in the training plan.

One of these research objectives was to reduce the overtime by 16%. In the beginning on May 2014 the overtime was on 26% overtime, on February 2015 the overtime was reduced by 6%. This was 4% better that the objective.

In control phase the team members will create a weekly overtime (This include DTI, OTI, 7th Day and MEA) and headcount report, this will be discussing in the team member meeting. 10% is the trigger limit to generate an action plan for the next week.

As overtime produced for one week Figure #5, represents the overtime generate per each supervisor for a week. Figure # 6, represents the double overtime (DTI), 1.5 overtime (OTI), meal penalty (MEA) and 7th day overtime (7th day DTI) generate by each supervisor for a week.

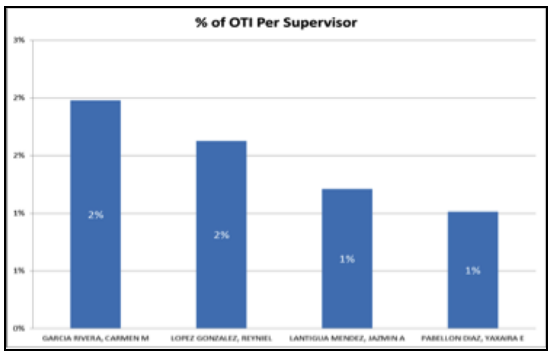

Figure 5
% OTI per Supervisor

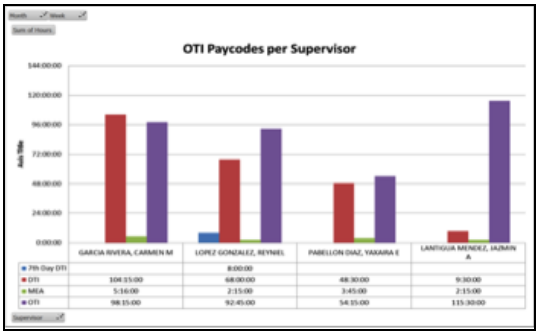

Figure 6
OTI Pay Codes per Supervisor

CONCLUSION

After the DMAIC process was completed, the team members analyzed and implement all the strategies to reduce overtime in clean room department. The clean room had a high absenteeism that was covered with the cross training. Before clean room department lose the three (3) employees, they trained another employees in their certifications, this plan was covered in the training plan.

One of these research objectives was to reduce the overtime by 16%. In the beginning on May 2014 the overtime was on 26% overtime, on February 2015 the overtime was reduced by 6%. This was 4% better that the objective. The team members must have to control this overtime creating an analysis to calculate the overtime weekly and this overtime must be under the 10%. Cross training was implemented between new hire and experiences employees to cover absenteeism in the clean room department.

REFERENCES

[1] T. Pyzdek. (2010). Six *Sigma Handbook: A complete Guide for Green Belts, Black Belts and Managers at all Levels* (3rd Edition.) [Online]. Available: http://accessengineeringlibrary.com.

[2] T. McCarty, L. Daniels, M. Bremer and P. Gupta. (2005). Six *Sigma Black Belt Handbook (Six Sigma Operational Methods)* [Online]. Available: http://accessengineeringlibrary.com.

[3] T. Pyzdek and P. Keller. (2013). *Handbook for Quality Management: A Complete Guide to Operational Excellence* (2nd Edition) [Online]. Available: http://accessengineeringlibrary.com.

[4] L. Wilson. (2010). *How to implement Lean Manufacturing*. [Online]. Available: http://accessengineeringlibrary.com.

[5] R. Hayler and M. Nichols. (2005). *What is the Six Sigma Process Management Methodology*? [Online]. Available: http://accessengineeringlibrary.com.

[6] J. Juran and J. De Feo. (2010). *Juran's Quality Handbook: The Complete Guide to Performance Excellence* (6th Edition) [Online]. Available: http://accessengineeringlibrary.com.