Production Optimization in the Packaging and Inspection Process at a Thermoforming Area

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Abstract *— This research is conducted in a manufacturing packaging company that makes the packages (plastic trays) for medical device companies. It is intended to increase the packaging and inspection production line by considering a new layout design and utilization of the resources. The methodology used in this project was the Lean Six Sigma including the DMAIC model. The objective was to increase the total production by 10%. Results showed an incremental percent of 15.25%. The takt time for the production line for packaging and inspection was proficiently decreased. Within the new arrangement the company has the capability of a crew reduction of an average of 4.5 unnecessary operators. After calculating the cost opportunity, in terms of incremental output, the saving was $24,246 plus the applied personnel reduction saving was $60,000. The total savings for the implemented project of $84,246 was applied to direct labor costs.*

Key Terms *— DMAIC, Lean Six Sigma, Packaging and Inspection Optimization, Production line, Thermoforming.*

INTRODUCTION

All product manufacturers are directed to produce in a high optimization environment to increase productivity. Effective resource organization can be influential in achieving this goal. The manufacturing industries establish step-by-step problem-solving methods that required them to think about the problem in new ways and the packaging companies for Medical Devices are not the exception.

Through the manufacturing of a package for a Medical Device it is important to consider the quality that the package must provide to the medical device company. The medical device industry is a direct customer of the packaging companies, by needing the package that contains the medical device as part of the final product to be delivered to the final customer. Having this high demand from the Medical Device Industry in contemplation the packaging companies need to make changes in the organization, especially in production. Taking this under consideration, a project for the optimization of production line is constantly needed to approach important areas of packaging production that will initiate changes and keep to maintain satisfying the demand to the customers; that are the Medical Device companies.

Research Description

Selecting the right opportunity for improvement in the industry is required to ensure the best possible results. This research was conducted in a packaging company that makes the packages (plastic trays) for the medical device companies. The main concern in the packaging company is the issues that are affecting the resources in the work place area organization, concerning the resources of labor, material, money and equipment. The researcher will be focusing optimizing these main resources.

The project optimization will be implemented in the labor resource of inspectors and packagers in the operation line and the equipment and facilities of thermoforming area. This will have a significative impact in the benefits of the company's capital. This project design is intended to optimize the production in a packaging and inspection process at the thermoforming area. It is intended to increase the packaging production by considering the new layout and utilization of the resources. By analyzing the labor resource in production line of packaging, specifically the packagers and inspectors the researcher will be able to increase the productivity in the company. As a result of analyzing the layout design of the work stations in which the packagers and inspectors of the plastics trays packing for medical devices are working, the researcher can measure the impact in the levels of productions. The researcher wants to measure the production of the line in terms of the resources. The packaging company has to increase in the production and to reach this goal of the project the DMAIC methodology approach will be use to present this research.

Research Objectives

The main objective to accomplish in this research is to increase the production by 10% in a packaging and inspection line of the thermoforming area of a packaging company for Medical Devices, without increasing costs of resources. Determine the quantity of operators by establishing a head count distribution in the production line of packaging and inspection process. Optimize the resources of labor and reduce cost of production. Reduce the takt time that takes to finish a box in the production line at the thermoforming area. In addition, it is projected to have a significant impact in the output of the units made by shift. Reorganize the work place area for the production line in the packaging and inspection process.

Research Contributions

This research will contribute in a cost-effectively and economically process for a packaging and inspection operation. The main contribution that will provide this research is labor organization in the thermoforming area. Another contribution is to enhancement the operators labor pride, responsibility and affection for the job performed. Develop valuable job skills such as decision-making, problem solving and teamwork. The company’s capital will have a significative impact in quantitative benefits. By the implementation of Lean Six Sigma in the project optimization of a packaging line, the company can become more profitable in terms of lower cost, improve delivery time and increase customer satisfaction.

Research Background

This section provides the concise information of all the knowledge that comprehends this design project. The specific research area in which is going to be developed this design project is the thermoforming area of a packaging company for Medical Devices. This research used the Lean Six Sigma methodology as a manufacturing tool to optimize the production line.

Medical Device

According to the FDA in the definition of the section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food And Drug Administration (FDA) as a medical device and is subject to premarketing and post marketing regulatory controls if a device is: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." [4]

Packaging

A package can be identified as a protective form or container for the product. “Packaging is best described as a coordinated system of preparing goods for transport, distribution, storage, retailing and use. In its most fundamental form, packaging contains, protects/ preserves, transports and informs/ sells. Protect refers to the prevention of physical damage, while preserve refers to stopping or inhibiting chemical and biological changes. Packaging is a service function that cannot exist by itself; it needs a product. If there is no product, there is no need for a package. Packaging managers need a basic understanding of both marketing and technical needs, mixed with good business sense." [3] The Figure 1 shows the product at the moment it is exposed in the production line, after undergo the thermoforming process.

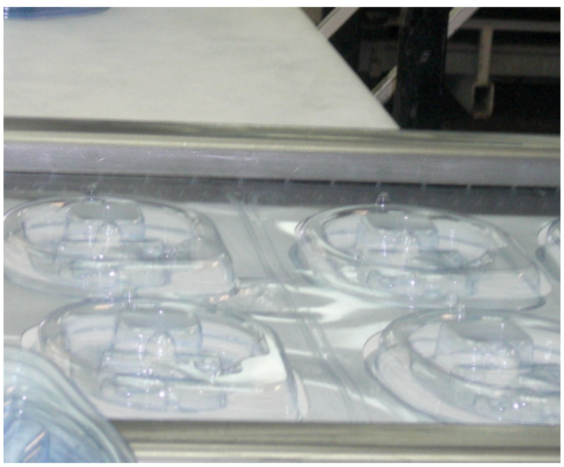

Figure 1
Product (plastics tray)

In this project the manufacturing company transforms the raw material of plastic into a finish product, created into a plastic package for a medical device.

Thermoforming area

The specific research area in which the optimization takes place is in the thermoforming area.

"The thermoforming is a process in which a flat thermoplastic sheet is heated and deformed into the desired shape. Thermoforming consists of two main steps: (1) heating and (2) forming. Duration of the heating cycle needed to sufficiently soften the sheet depends on the polymer- its thickness and color. The methods by which the forming step is accomplished can be classified into three basic categories: (1) vacuum thermoforming, (2) pressure thermoforming, and (3) mechanical thermoforming. The starting sheet or film is rapidly fed through a heating chamber and then mechanically formed into the desired shape." [2] (See Figure 2).

In the packaging company the thermoforming method in which the package forming is accomplished is the pressure thermoforming. This method involves the positive pressure to force the heated plastic into the mold cavity. The Figure 3 shows the final package product (plastic tray) at the end of the production line, after undergo the thermoforming process.

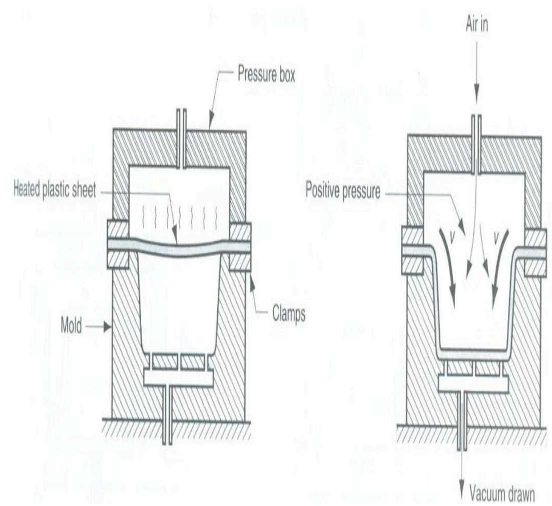

Figure 2
Pressure thermoforming process

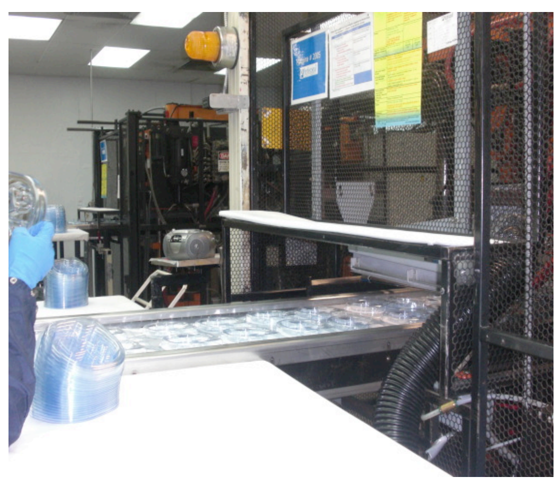

Figure 3
The end of the production line

Production line

The optimization of this project took place in the production line of a packaging and inspection process of the thermoforming area. Each production line of the company consists of one thermoforming machine and at the end of this process it has inspectors and packager operators. In total, the packaging company counts with 5 thermoforming machines: 3 smalls and 2 large ones.

"Production lines are an important class of manufacturing system when large quantities of identical or similar products are to be made. In a production line, the total work is divided into small tasks, and workers or machines perform these tasks with great efficiency. A production line consists of a series of workstations arranged so that the product moves from one station to the next, and at each location a portion of the total work is performed on it. Production lines are associated with mass production. The high-quantity range (10,000 to millions of units per year) is referred to as mass production" [2]

Lean Six Sigma Methodology

In an industry of constant change you have to attack the issues that are presented in the product production. In Lean Six Sigma methodology it is important to make a list of my priories and analyze each process by their cost opportunity. There is a need for the Lean Six Sigma implementation in any area of work in the industry.

"Lean Six Sigma is a methodology that maximizes shareholder value by achieving the fastest rate of improvement in customer satisfaction, cost, quality, process speed, and invested capital." [1]

The most efficient path to follow a structured improvement method that leads to a logically definition of the problem to implementing solutions that address the underlying causes is the most widely used improvement model DMAIC. It is identify as a traditional define, measure, analyze, improve and control DMAIC Six Sigma strategy: "Define: Confirm the opportunity and define the boundaries and goals of the project. Measure: Gather data to establish the "current state", what is actually going on in the workplace with the process as it works today. Analyze: Interpret the data to establish cause-and-effect relationships. Improve: Develop solutions targeted at the confirmed causes. Control: Implement procedures to make sure the improvements/ gains can be sustained." [1]

The utilization of these application concepts in the design project for the optimization of the production in the thermoforming area will present a significative impact and improvement in the packaging and inspection line.

PROJECT METHODOLOGY

To develop and accomplish the objectives established in the problem statement the methodology to be used in this project is the Lean Six Sigma methodology. The path to implement solutions and address the underlying causes of the problems in the methodology is to follow the improvement model DMAIC. The steps for DMAIC, are to follow a structured, data based problem-solving process.

RESULTS AND DISCUSSIONS

The results obtained in this project were following the improvement model DMAIC.

Define

Four different manufacturing products (plastic trays) were selected to perform a monitoring system and quantify the increased productivity of the line. To measure and analyze the takt time the researcher took the time to complete a finish box of product between each performed.

The study was divided in two phases: examine the actual state and the expected state with the changes made in the work place area. The Figure 4 shows the actual process map production line at a Thermoforming area.

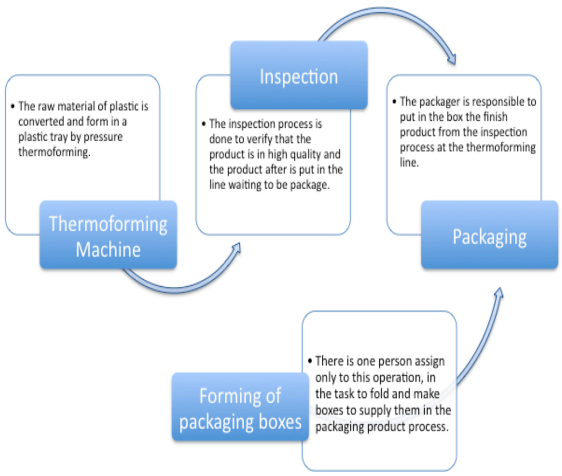

Figure 4
Actual Process Map

Measure

The actual state of the packaging and inspection line in the thermoforming area was established by gathering all the data of the production line of packaging and inspection. By measuring the time of each plastic tray produced or manufactured during an hour in the study the current and new state was established.

The researcher observed the packaging and inspection process to establish a deep map of the process. The most important workplace organization proposed in the new design is to inspect and pack the product that comes out of the thermoforming machine using the same person. In this manner, the production used a positive flow of movement.

Acquiring the line production standards for production for the packaging company the researcher was able to compare the actual production versus the new proposed arrangement in the packaging company. Also, the researcher was able to make comparisons between the standard of production established and the new output.

In accordance with the objectives, it was measure: the production in the line, the takt time in minutes per box in the line and the operators distribution in the production line of packaging and inspection. The three aspects where measured and considered in the Tables 1-3 as follows:

Table 1
Actual production per 6.5-hour shift

Production Measured in the Actual Arrangement at the Packaging and Inspection Line in Units of Plastic Trays Per 6.5 Hour Shift				
	Product 1	*Product 2*	*Product 3*	*Product 4*
Actual Production	8,840 units	4,472 units	19,175 units	10,881 units

Table 2
Actual takt time to finish product box

Actual takt time in minutes that takes to finish a product box in the packaging and inspection production line				
	Product 1	*Product 2*	*Product 3*	*Product 4*
Actual takt time	7.5	4.583	4.176	5.114

Table 3
Actual operators distribution

Operators distribution in the actual arrangement in the production line of Packaging and Inspection				
	Product 1	*Product 2*	*Product 3*	*Product 4*
Actual State of Production				
Inspectors	3	2	2	2
Packagers	1	2	2	1
Forming Boxes	1 for all the products lines			

Analyze

In this phase the results obtained were analyzed upon the proposed new arrangement, which was implemented in the company (see Table 4 and Figure 5).

Table 4
New arrangement comparison with actual production

Production measured at the Packaging and Inspection Line in units of plastic trays Per 6.5 Hour Shift				
	Product 1	*Product 2*	*Product 3*	*Product 4*
Actual Production	8,840 units	4,472 units	19,175 units	10,881 units
New Production Arrangement	10,452 units	5,570.50 units	20,800 units	11,934 units
Difference	1,612 units	1,098.50 units	1,625 units	1,053 units
			Average Difference	1,347.13 units

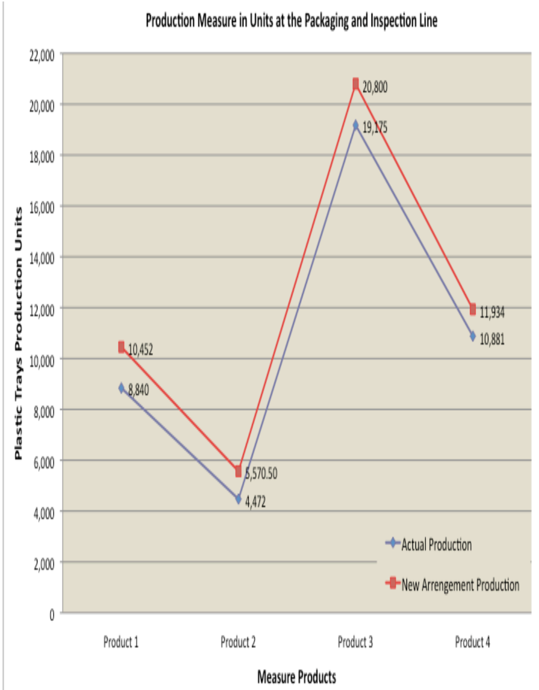

Figure 5
Graphic of the production measured in units

The total increment percent obtained in the production was 15.25 (see Table 5). This increment in production was obtained due to the changes made in the new layout design for continuous flow of the production line.

Table 5
Increment percent in production

Incremented Percent (%) in Production at the Packaging and Inspection Line Process Per 6.5 Hour Shift				
	Product 1	*Product 2*	*Product 3*	*Product 4*
Incremented % with New Production Arrangement	18%	25%	8%	10%
			Incremented Average %	15.25%

The new production arrangements measures of the units of plastic trays made per 6.5-hour shift where compare with the standard that is establish in the company (see Table 6). As results in each new production arrangement were higher than the company's production standard. In this matter with the new production arrangements ensure that the standard is met.

Table 6
New Production comparison with standard

Production of the new arrangement versus the production standard measured at the Packaging and Inspection Line in units of plastic trays Per 6.5 Hour Shift				
	Product 1	*Product 2*	*Product 3*	*Product 4*
New Production Arrangement	10,452 units	5,570.50 units	20,800 units	11,934 units
Production Standard	8,000 units	5,500 units	15,000 units	10,000 units
Difference of the new Arrangement vs. the Standard	2,452 units	70.50 units	5,800 units	1,934 units
			Average Difference	2,564.13 units

A new head count of the numbers of operators in the packaging and inspection process was established to optimize the labor and reduce this cost. The results that appear in Table 7 are based upon the actual production arrangement versus the new arrangement. After the changes made in the new production arrangement layout and a redistribution of labor duties, it was possible to reduce an average of 1.5 operators per 6.5-hour shift. Considering that the thermoforming area runs a 3 shift per day, the company has the potential to reduce up to 4.5 unnecessary operators from the packaging and inspection process.

Table 7
Distribution of operators in production

Operators distribution arrangement in the production line of Packaging and Inspection per 6.5 hour shift				
	Product 1	*Product 2*	*Product 3*	*Product 4*
Actual Arrangement of Production				
Inspectors	3	2	2	2
Packagers	1	2	2	1
Forming Boxes	1 for all the products lines			
Total Operators	5	5	5	4
New Arrangement of Production				
Inspectors	3	2	3	1
Packagers	1	1	1	1
Box Forming	0			
Total Operators	4	3	4	2
			Average Operators difference	1.5 per shift

The new arrangement was measured to analyze the time it takes to finish a box in the packaging and inspection process. It was compared in Table 8 with the actual values.

Table 8
Mean time to finish a product box

Actual and new arrangement takt time in minutes that takes to finish a product box in the packaging and inspection production line					
	Product 1	*Product 2*	*Product 3*	*Product 4*	*Average takt time*
Actual arrangement takt time	7.5	4.583	4.176	5.114	5.34
New arrangement takt time	6.509	3.713	3.901	4.858	4.75

An hypothesis test was conduced to verify and analyze the takt time that takes to complete a finish box of product in the expected state is less than the actual takt time. Between each perform inspection and packaging process to finish product, the appropriate percent of confidence was established with the takt time of each four products. To verify the takt time that takes to complete a finish box and the percent of confidence, the T Test was used. For project purposes the example of hypothesis for Test T will be explained for one of the four products. The takt time specification is 7.5 for the actual state and is 6.509 for the expected state, n is 8 and 9 respectively and the percent of confidence is explained.

- **Hypothesis conclusion:**

The experimental T in the four products are T exp1 = -0.783 in which is significant at a 78% of confidence, T exp2 = -1.007 in which is significant at 84% of confidence, T exp3 = -0.287 in which is significant at a 61% of confidence and Texp4 = in which is significant at a 67% of confidence (see Table 9). The percent of confidence established represents the percent of success it is going to be repeated the takt time per box.

Table 9
Hypothesis Test T

Hypothesis Test T				
	Product 1	*Product 2*	*Product 3*	*Product 4*
T experimental	-0.783	-1.007	-0.287	-0.454
Confidence %	78%	84%	61%	67%

Improve

The results presented were possible due to an effort of ideas by the operator's, managerial and engineering experience presented in the brainstorming. It was essential to understand what going on in the thermoforming area to bring positive effects in the process. The causes that were found as a result of the brainstorming are included in the fishbone diagram (see Figure 6). It was significant to interview the production personnel to comprehend in detail the packaging and inspection process, therefore a cause and effect analysis could be done successfully.

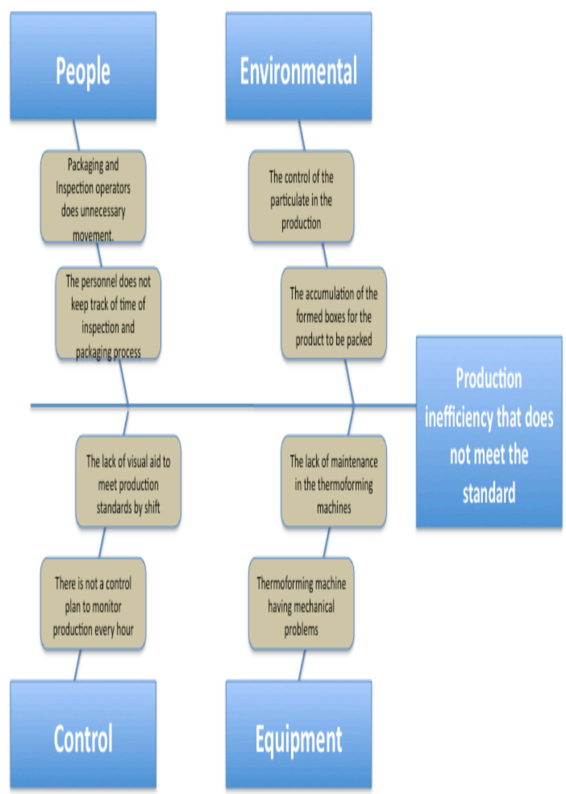

Figure 6
Fishbone Diagram

- **Brainstorming:**

Taking in consideration an evaluation based in the most cost effective solutions the ideas and areas of opportunities were established. Some of the ideas presented in the brainstorming were analyzed in a prioritization form. It was established as necessary the increase of production, determine the production by shift, and reduce the head count operators personnel. The Figure 7 shows the best improvement model with the new production layout. The Figure 8 illustrates the new arrangement process map of the production line at a Thermoforming area.

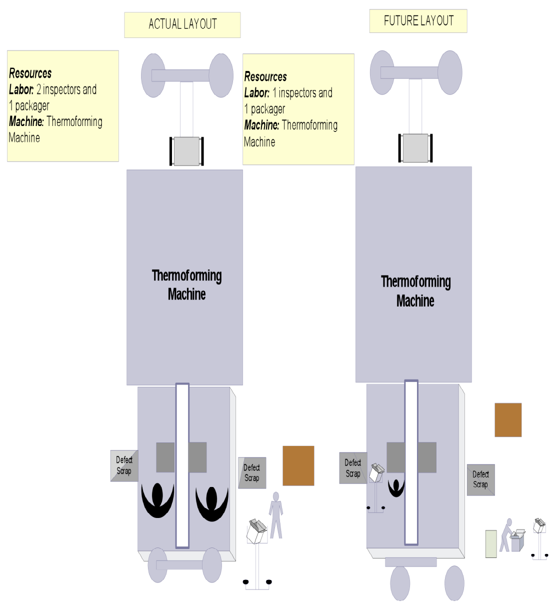

Figure 7
Example of the New Arrangement Layout

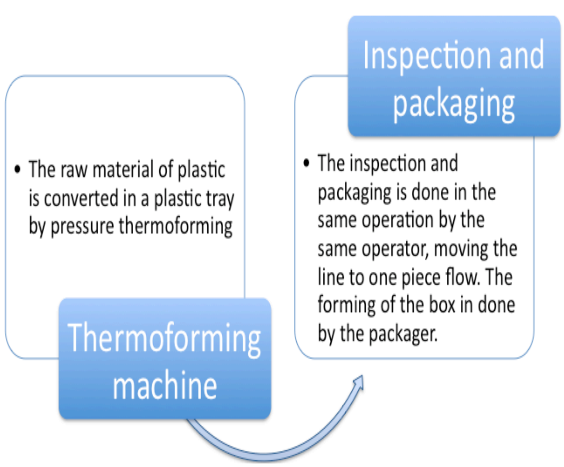

Figure 8
New Arrangement Process Map

- **Project Management:**

In consideration of the evaluation of the most cost effective solution, it was essential to share these ideas with the Management of the Company. In this manner it was important to point that to start this optimization in the production, it requires cero capital inversion and furthermore no money need to be invested to obtain a direct increment and profit.

- **Cost improvements in the incremented production:**

The improvements made in the actual arrangement versus the new arrangement were a 15% in increment in the production. Considering the average 3.25 operators per shift in the new arrangement, the operators are paid on an 8-hour shift an average of $10 per hour including benefits; it has a $260/shift. Taking the actual production measure of the products the average actual production is 10,842 units. To find the labor cost per piece the $260/shift was divided with the 10,842 units to have a $0.024 per piece. The Table 10 shows the average increase production difference. Multiplying the average increase production difference of 1,347.13 with the labor cost per piece of $0.024, the incremented production labor cost per shift is $32.33. The company runs three shifts per day within 250 working days a year, to quantify a total production incremented of $24,246. This means the increment of 15% in production; the company will have an estimated $24,246 of savings.

Table 10
Average increase production

Production measured at the Packaging and Inspection Line in units of plastic trays Per 6.5 Hour Shift				
	Product 1	*Product 2*	*Product 3*	*Product 4*
Increase production difference	1,612 units	1,098.50 units	1,625 units	1,053 units
			Average Difference	1,347.13 units

- **Personnel reduction savings:**

The potential personnel reduction with the new arrangement is 1.5 operators per shift; analyzing the 3 shifts per day it will total 4.5 operators. The personnel reduction savings were analyzed based in the company's paid 8-hour of production, the labor average cost of $10.00 including benefits and 250 workdays. The company decided to reduce personnel with the new arrangement design 3 operators. The annual savings in reduction of personnel, in terms of operators are a total $60,000.

After calculated the savings in terms of incremented production of $24,246 and the personnel reduction savings of $60,000, within my project the company will save an estimated $84,246.

Control

The control step is fundamental in sustaining the changes made and suggested in this project. It is the path to maintain the implemented solutions and the addressed causes of production problems in the packaging and inspection line. Having this under consideration is necessary to develop a process flowchart to visualize the production line in the packaging and inspection line in the thermoforming area. A process flowchart will help know the operators and the management by each hour the production, in terms of the quantity of boxes that comes out of the packaging and inspection process line.

Taking the information available the top method to ensure that the increase in production will sustain, the mean time it takes to finish a product box will maintain the same or decreasing and that all the people take the same time in the production line, is to establish a process of monitoring system. This is critical after a change is made and implemented. Also, by establishing a monitoring system it can be validated the optimizations executed and specify the main causes underlying this project where productively address.

CONCLUSION

In accordance with the objectives, increase the production by 10%, reduce the takt time in minutes that takes to finish a box, change operator's distribution in the production line for packaging and inspection. These three (3) aspects were completed and accomplished in the production new layout and work distribution in the packaging and inspection line for the thermoforming area.

The main objective of this project was to increase the production by 10% and the total increase percent (%) obtained in the production was 15.25%. In this aspect, this project provides the necessary information to prove that the standard of production of plastic trays produce per 6.5-hour shift establish can be revise and increased, to maintain a competitive price in the market. The new increase production standard can be considered as follows: product 1: 10,000, product 2: 5,550, product 3, 20,500 and product 4: 11,500.

An other direct result was the reduction of the cost for labor. A head count of the numbers of operators in the packaging and inspection process was established to optimize the resources of labor and reduce cost of production by 1.5 operators per shift. Considering the total reduction and incremented production the alternatives developed it achieved cost savings for the company of $84,246 in direct labor.

One recommendation for the company will be consider the position of group leader for performing labor of inspection and packaging.

- **Future work:**

During the development the researcher identified areas of future opportunities such as the formulation of metrics to measure productivity. The packaging company can assure the consistency in the production and maintain a competitive price in the market. Also, considering future work in the packaging company it is proposed another project to implement a scrap control monitoring system.

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