

QC Downtime on Work - Orders of 100 Pieces or Less for Packaging/ Boxing Area

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Abstract — *In this investigation you will obtain information about a continuous improvement methods: the A3 Project application. This method follows the Plan Do Check Act (PDCA) cycle which will be conducted in the production lines for the first time in a high production medical device company. It will be focused on reducing the downtime generated in the packaging areas by the quality control (QC) inspectors in works of less than 100 pieces while allowing the inspections to be completed with a high quality. After several modifications with personnel from different areas such as: Planning Department, Quality Department and Packaging Department as well, was obtained an agreement in increasing amount of jobs and updated inspection sheets to standardized inspection processes facilitate inspectors tasks. Standardized inspection processes were also obtained. All the changes performed contributed notably to a significant reduction of downtime allowing the company to achieve a higher customer satisfaction and rating.*

Key Terms — *A3 Project, DMAIC (Define-Measure-Analyze-Improve-Control), Lean Six Sigma, PDCA (Plan-Do-Check-Act).*

SUMMARY

In this research you will find information about the possible improvements that can be made in high production companies through the application of A3 Project: Plan Do Check Act (PDCA) Method by the first time. This research will be focused on reducing the downtime process performed in production areas in jobs less than 100 pieces. It will also be based on improving the inspection process in production areas in order of accelerate the production flow to complete properly the product assembly which contribute to make this a satisfactory delivery to the customer. During this

research, we will considered the amounts of the work orders, time of delay to carry out inspections by Quality Control (QC) Inspectors including 1st piece, Acceptance Quality Level (AQL) samples and Boxing to improve the steps performed with different devices in a manner that accelerate and facilitate the production process- which are responsible of receiving components and assemble them to be packed. It is also important to mention that during packaging process will be evaluate the every step performed in a way that if there is an alteration it can be solved easily without affecting the work flow. Through the analysis of these processes, it will be possible by a very first time to demonstrate the possibility of using a general methodology of a continuous improvement cycle in a manufacturer organization but using an A3 Project process. It is PDCA which was created by the Control Chart's dad, Walter Shewhart [1] [2]-[3].

PROBLEM STATEMENT

The quality group of the company is experiencing on a daily basis a non-comfortable work environment due to unnecessary work overloads and processes that could affect the well-being of the employee, time management and increase costs due to reworked jobs, scrap material, issues with Bill Of Material's (BOM), Non-Conformance during the processes, etc. All this processes are affecting production and even causing possible delays to the customers.

From that, we would highlight in this investigation the time loss that occurs almost daily in the production areas and demonstrate that with the implementation of PDCA with an A3 Project method, a big percentage of downtime during the production process would be reduced and, therefore, expedite it. In addition be able to implement risk-

based inspection in which inspectors will be able to alternate the path (maintaining high quality) to solved any issue that appear during the production and the final product can be released easily, boxed and shipped to keep a high customer satisfaction.

The PDCA method is going to be applied in this investigation to demonstrate how it could be modified in such a way that large production companies do not exclude it from their processes.

RESEARCH DESCRIPTION

By obtaining this research, it will become possible to expand the capacity of the PDCA, a continuous improvement methods based on Six Sigma application in the manufacturing industries of medical equipment in controlled environment areas.

RESEARCH OBJECTIVES

The purpose of this research is to reduce the amount of downtime on production lines with jobs of a hundred pieces or less. It will also conducted to avoid time wastes during inspection processes followed in a daily base by QC Inspector in the company due to the constant components been found with discrepancy in packaging area. Another effect that affect the direct work flow and increase costs are the different tasks that every inspector needs to performed according procedures. To make this research feasible, it will be necessary to:

- Evaluate the 1st Piece, AQL samples and Boxing inspection process.
- Create problem-solving techniques to identify root causes and eliminate 50-80% of downtime.
- Reduce QC Inspector tasks during work production.
- Process and boxed work orders with agility without downtime but with a high quality parameter of zero defects.

RESEARCH CONTRIBUTIONS

Obtain a new perspective using PDCA as a continuous improvement method in order to achieve agility in the inspection processes to be able to satisfy the customers with high quality and fast delivery.

LITERATURE REVIEW

This research shows an A3 project based on PDCA realized at a company dedicated to the manufacture of orthopedic medical equipment. Those are inspected / tested about 4 times as per certain procedures to determine if they are accepted or rejected, to reach the final stage of the product packaging process, and shipped to the customer. Every day, since the great organized management, is being produced approximated 120 work orders in both clean-rooms. A total of 32 work orders have a hundred pieces or less, which can create delays in the work flow due to all the tasks that quality inspectors need to perform and makes it impossible for a fast shipment to the customers, process that can affect the customer's satisfaction and in addition, generates increase in costs. For this reason, it is important to determine the main problems, causes and effects to decrease the downtime.

Plan-Do-Check-Act (PDCA) is a cycle of four steps designed to improve and obtain changes in a process. PDCA implementation based on continuous improvement methods will allow to determine the principal factors of process failures causing delays/ downtime and to discover opportunities for improvement. The improvement will be focused on reducing downtime on production line at least a 20% while conducting inspections to accelerate production work flow. It is expected to be able to demonstrate a way to consider Six Sigma method and allow it to be implemented open-wide on big manufacturers since PDCA is much related to it [4] [5] [6].

INTRODUCTION

To improve the processes in a manufacturing company is, without a doubt, one of the key elements to obtain very successful results and a great satisfaction to the customers. For that reason is very important to keep improving continuously all the areas/ departments that make possible to obtain excellent results. One of the methods used for quality management is PDCA cycle, a continuous improvement cycle with a main goal to minimize defects and variation in the inspection process, acceptance and assembly of the product [7].

According Hwaiyu Geng et al. (2005), this method is one of the best strategies of continuous improvement to discover the causes of defects and delays in the processes of a company. The objectives of this research will be achieved by obtaining measures from the current processes been performed, failure analysis and improvement alternatives on production lines: the most important areas or processes to carry out the improvement plan; design a plan to address each of the areas for improvement, be clear to the people responsible for carrying out the study and follow-up of the improvement action, schedule well the deadline for its implementation and be clear that resources will be needed to take it to practice [8].

In order to obtain successful results when making an improvement plan, it is necessary to create an organizational plan. However, it is therefore necessary to consider the weaknesses of the processes (what needs to be improve to achieve the objectives). After performing these steps, it is very important to evaluate the other aspects or areas that would benefit at the end of the cycle.

This is not just a research but, a plan of improvement in which it is necessary to reflect, analyze, and be able to obtain a result of a previous analysis and endowed with a certain realism, without forgetting that it is to be successful in the processes.

The measured objectives will be based on whether the current inspection system in work

orders with quantities less than 100 pieces providing a reliable estimate based on a high quality product while reducing or eliminating downtime in the production lines. In relation to the method of analysis of downtime failures, several objectives were established: a) to evaluate the origin of failures in work orders ≤ 100 pieces; b) to increment quantities of work orders; c) Improve documentation (In- process(IP) Sheets) to sample the parts and obtain a reliable estimate of the parts; d) standardize the analysis of assembly processes making all the inspectors perform their tasks in the same way; e) to propose an alternative method for the analysis of defective parts before reaching the packaging process. Regarding the analysis of problems and improvement of the process, the objectives will be: 1) identify and evaluate when the effects of the sources of variation would be minimized; 2) standardized inspection process; 3) develop improvement proposals and 4) implement and monitor proposed improvements.

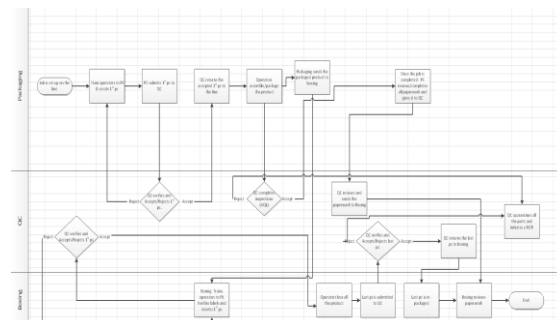


Figure 1
Current Work Flow

METHODOLOGY

The best known cycle in continuous improvement methods is DMAIC: Define, Measure, Analyze, Improve and Control. It is a continuous improvement cycle based on Lean Six Sigma to be applied in new processes. However, another method is through the use of A3 project. An A3 project is no more than the ability to present the project on an 11x17 size paper. Is a systematic problem solving which it's generally used in organizations guided by Lean Six Sigma-which is a methodology used to reduce waste in companies to

obtain process improvements and be successful. It is normally used to obtain, interpret and analyze easily the results of a continuous improvement project. According to Deming, the PDCA (Plan, Do, Check, Act) is a strict, strategic and organized cycle used to obtain a progress of the current processes. This methodology will be followed in order to achieve the objective of the research by reducing downtime on production line in work orders ≤ 100 pieces.

Plan: When performing this phase, should be develop a plan of actions based on a specific calendar and resources. The proposed improvement, the process mapping, should be specifically explained, based on customer satisfaction.

From the Brainstorming was obtained a fishbone chart seen on Fig. 1.

Do: To put the plan in action. It will be necessary to evaluate the current processes performed in cleanroom areas, as well as processes to inspect the components. Stipulate a strategy to obtain quantifiable results in the progress of the objective. Data will be documented based on the

process performed, brief description of the problem without ignoring procedures established by the company (segregate bad-parts, labeled them, complete a non-conformance report).

Check: Refer to the results obtained in order to detect to what extent the objectives have been met. The result obtained will be the theory proven and confirmed, confirming the needed information to collaborate with the phase of improvement. It also will be evaluate the plan and the solutions to keep continuous implementation and a standardize the process. A monitoring system will be established. Results, learning and recommendations will be documented.

Act: This consists of being able to learn from the results obtained; In other words, to know the specific areas in which improvements will be carried out, detected in the verification phase in order to implement actions that overcome them. The PDCA cycle; as mentioned above, it is called a circle of continuous improvement, since after the last stage, the planning phase begins again, this time with valuable information on the resources obtained in the previous planning [9].

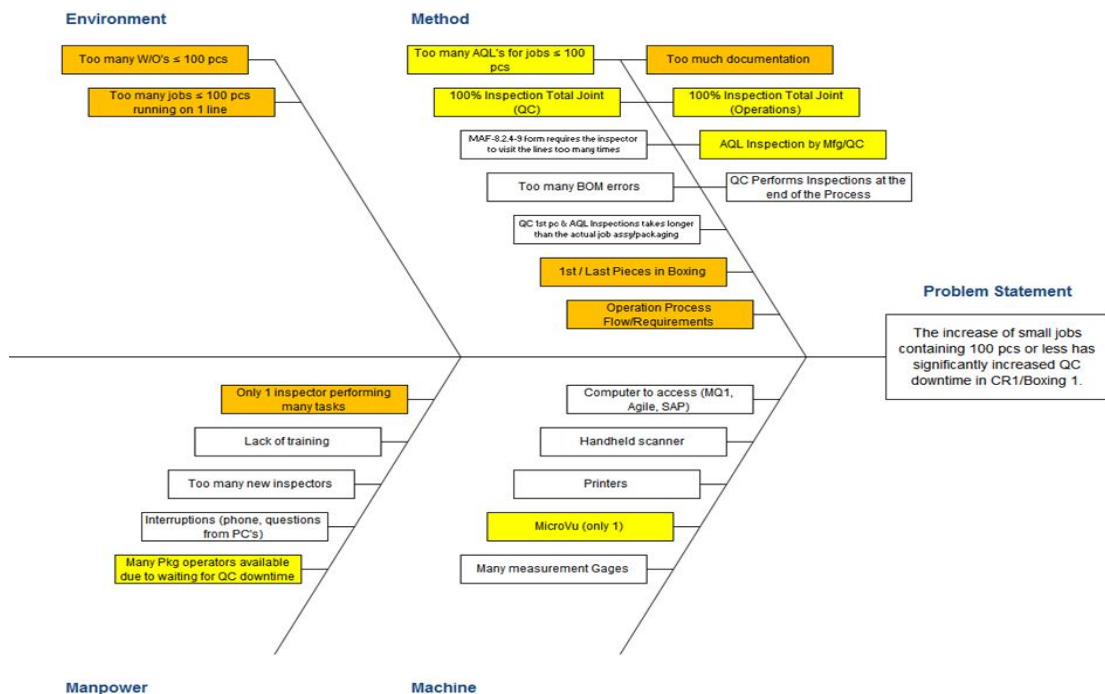
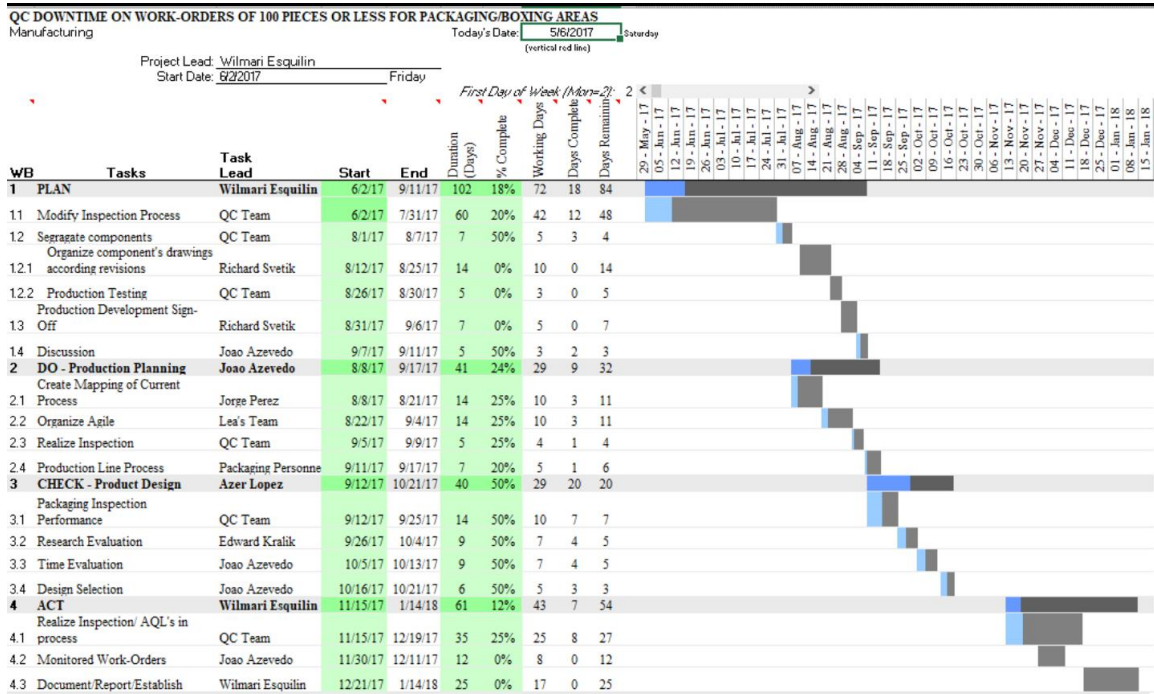


Figure 2
Fishbone Chart

RESEARCH SCHEDULE

To obtain a great result from this research was created a Gantt Chart to get a forecast.

Table 1
Gantt Chart



RESULTS AND DISCUSSION

The methodology was carried out by the working group selected of Quality and Planning, department. This was realized as an analysis to detect and correct situations that were affecting the agility in the process of inspection and production/assembly. A map (Fig. 2) of processes was created to visualize clearly all the research landscape.

The tools used to identify the operations were:

- The Cause-and-Effect Diagram (Ishikawa)
- Pareto
- A3 Project Method

In the data analysis must also analyze the indicators of production:

- Count of debris
- Downtime
- Defects of quality
- Reprocessing

- Cycle time of a production

These data will be used as indicators of results of processes thus providing more value of the performance and behavior of processes.

From the solutions considered more acceptable, was developed the plan of implementation of improvements, considering at least the activity to implement, responsible, and resources to use. For this, it was necessary a discussion and generation of Brainstorming (Fig. 1) for the team, with the aim of creating a plan for improvement [10].

Other evaluations were used for hypothesis tests to determine in what direction the research would end.

RESULTS

To obtain a clear view of how it is everything being processes it is needed to create a Current Workflow from all the areas which are being

affected by downtime during inspection process, those were AQL Inspection Process Fig. 3; 1st pieces current process: Fig. 4; Boxing 1st & Last Piece Current process Fig. 5.

From the Brainstorming was obtained a fishbone chart seen on Fig. 2.

Below are presented the work-flow by areas:



Figure 3 Packaging In-Process Inspection

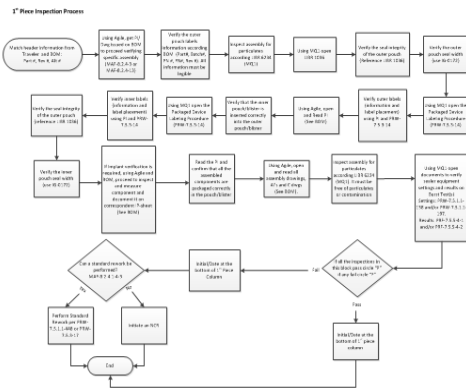


Figure 4 Packaging 1st-Piece Inspection Process

Even those are different areas, the process to realize the inspections are very similar to each other. In spite of having tried to reduce steps in the processes carried out in the different areas, these were not fruitful. All the steps stipulated in the procedure are duly conducted according to the regulations related to the equipment manufactured in medical equipment companies. Examples of these are: FDA (Food and Drug Administration),

ISO 13485 - which is what regulates that all equipment is safe and effective, among others.

To obtain these flows for every designed area was needed to take in consideration the production procedures. It was also necessary to verify how the QC inspectors realize their duties daily and compare it with the IP-sheets forms used by areas against the current procedures.

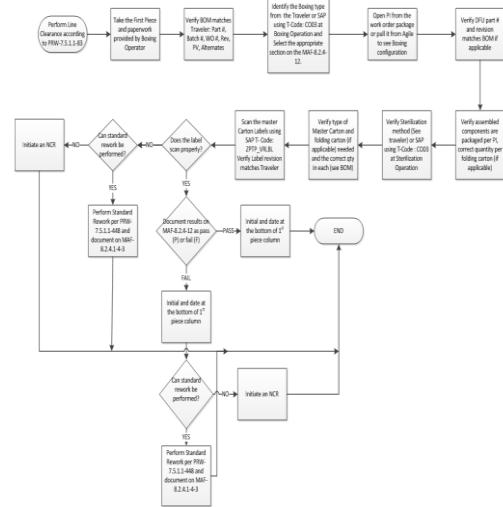


Figure 5 Boxing 1st-Last piece Inspection Process

After a period of 5 months data was obtained from a total of 28,811 jobs. See Table 2.

Table 2 Percentages of Work Orders Completed according Quantities

Quantities	Work orders completed	Percentages
≤ 100 pieces	10,372	36%
> 101 ≤ 500	13,541	47%
≥ 501 pieces	4,898	17%

In addition, another time study was realized to evaluate how long (Average Run Time) every process takes to be completed in the different areas. Several AQL samples were analyzed according to previous quantities evaluated in the project. An average was obtained between the period of time that takes to performed 1st piece and AQL samples

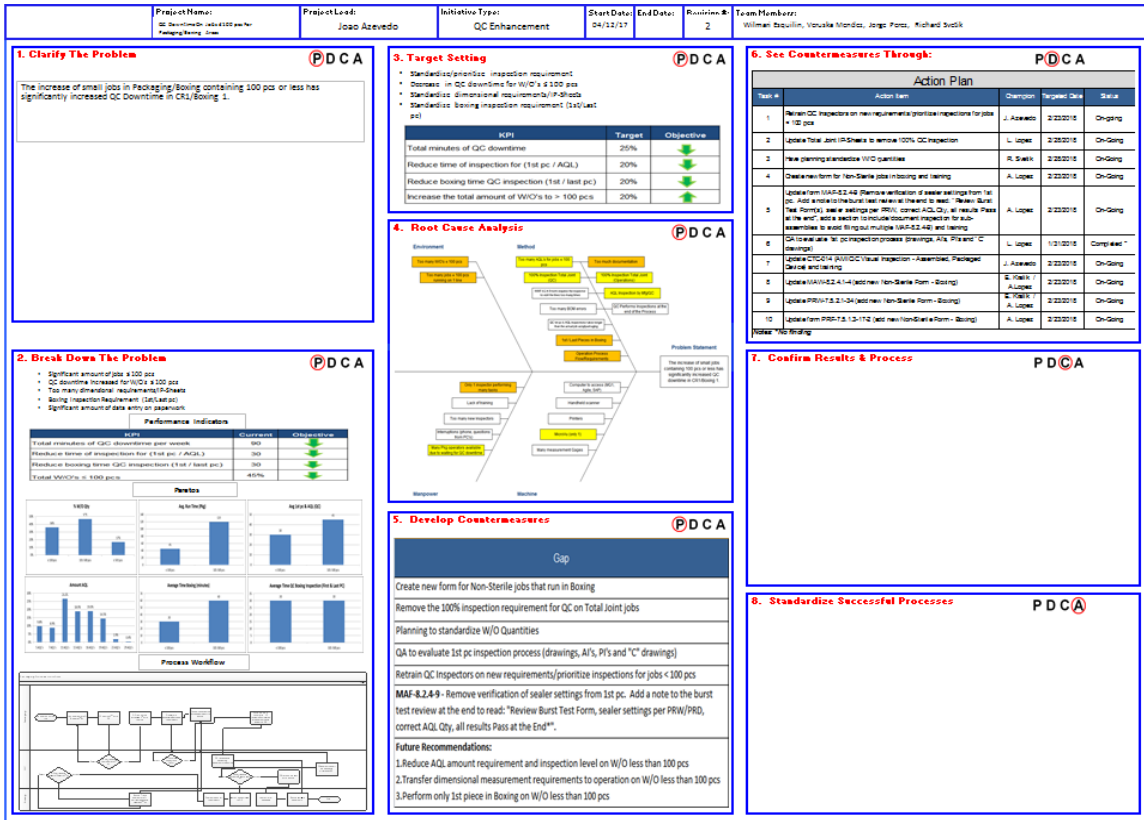


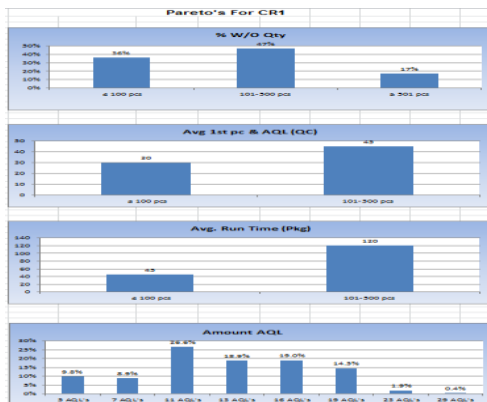
Figure 6
A3 Project

which was plotted on Graph 1 according the work order quantities. Comparing the results obtained between WO less than 100, WO between 101 to 500 and, WO more than 501 something could be noticed in which the management drew a lot of attention. The results obtained from WO less than 100 pcs and WO from 101 to 500 pcs were not very different. These were 36% and 47% respectively.

A3 Project Method: A very successful way to present a project in your company. On it you can present from the beginning of the research until the completion of it. All these in just one sheet.

According A3 Project Method, countermeasures were created and plotted on Table 3:

Table 3
Countermeasure



Gap	If We	Team Who
Create new form for Non-Sterile jobs that run in Boxing	Design an specific form for Non-Sterile jobs	Will perform QC Inspector's task easier and faster
Remove the 100% inspection requirement for QC on Total Joint jobs	Perform component inspection before piece head in packaging area and update P-Draws to guarantee that pieces are high quality assemble	Will be able to perform inspections and measurements in a faster manner
Planning to standardize W/O Quantities	Get Work orders at packaging area with big amounts (increasing am out of Lots)	QC Inspectors will be able to perform tasks with higher quality
Retrain QC Inspectors on new requirements/prioritize inspections for jobs < 100 pcs	Train inspectors to prioritize small work orders	And packaging personnel will be working in the same direction making everything be smooth
MAF-8.2.4-9 - Remove verification of sealer settings from 1st pc. Add a note to the burst test review at the end to read: "Review Burst Test Form, sealer settings per PRA/PRD, correct AQL Qty, all results Pass at the End!"	Are not responsible for verifying sealer settings	Will get 1st piece process shorter
Future Recommendations: 1. Reduce AQL amount requirement and inspection level on W/O less than 100 pcs 2. Transfer dimensional measurement requirements to operation on W/O less than 100 pcs 3. Perform only 1st piece in Boxing on W/O less than 100 pcs		

An action (Table 4) plan was created to combine the tasks with the research schedule (Gantt Chart) leading to reliable due dates.

**Table 4
Action Plan**

Action Plan				
Task #	Action Item	Champion	Targeted Date	Status
1	Retrain QC Inspectors on new requirements/prioritize inspections for jobs < 100 pcs	J. Azevedo	2/23/2018	On-going
2	Update Total Joint IP-Sheets to remove 100% QC Inspection	L. Lopez	2/28/2018	On-Going
3	Have planning standardize W/O quantities	R. Svetik	2/28/2018	On-Going
4	Create new form for Non-Sterile jobs in boxing and training	A. Lopez	2/23/2018	On-Going
5	Update form MAF-8.2.4-9 (Remove verification of sealer settings from 1st pc. Add a note to the burst test review at the end to read: "Review Burst Test Form(s), sealer settings per PRW, correct AQL Qty, all results Pass at the end", add a section to include/document inspection for sub-assemblies to avoid filing out multiple MAF-8.2.4-9) and training	A. Lopez	2/23/2018	On-Going
6	QA to evaluate 1st pc inspection process (drawings, AFs, PFs and "C" drawings)	L. Lopez	1/31/2018	Completed *
7	Update CTC-014 (AMI QC Visual Inspection - Assembled, Packaged Device) and training	J. Azevedo	2/23/2018	On-Going
8	Update MAW-8.2.4.1.4 (add new Non-Sterile Form - Boxing)	E. Kralik / A.Lopez	2/23/2018	On-Going
9	Update PRW-7.5.2.1.34 (add new Non-Sterile Form - Boxing)	E. Kralik / A. Lopez	2/23/2018	On-Going
10	Update form PRF-7.5.1.3-17-2 (add new Non-Sterile Form - Boxing)	A. Lopez	2/23/2018	On-Going

*Notes: * No finding*

Discussion

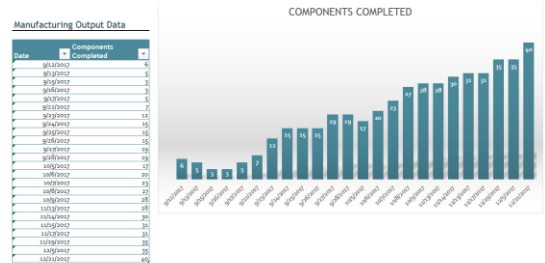
Up to this moment it has not been possible to complete all the plans stipulated to be carried out in the project. However, some of them have already worked. These are, to increase the quantities of the work orders to lots of larger quantities, the updates of the IP-sheets for the inspections carried out by the quality inspectors. Also the update of the In-process form eliminating the verification of the sealer machines, elimination of Total-Joints inspection in the packaging area, focusing only on the assembly of the product since the pieces have been inspected very detail oriented in the operations carried out before packaging area. Graph 2 reflects the changes happening throughout the project for approximated 6 months continuously.

On the other hand, after making an analysis as to how the inspectors carry out their work on a daily basis, it was concluded that monthly training is needed among QC inspectors in order to put into practice the correct ways to carry out the inspections, avoiding unnecessary steps (as looking for drawings of the components issued to the work orders, looking at SAP to verify batches issued to work order, etc.) and be able to standardize the inspection processes in the areas of packaging and boxing.

Therefore, it is estimated that if the standardized processes in the areas of packaging and boxing are kept in force, an optimal work flow can be obtained in which none of the areas is affected and the work orders can be completed in a maximum period of 90 minutes maintaining,

obviously, a high quality in the products to obtain maximum satisfaction of the client.

The next graph summarizes the results of the work orders finalized in the production lines with quantities ≤ 100 pieces in an average of 90 minutes.



**Graph 2
Manufacturing Data**

The image above shows a remarkable increment in the completed orders. It compares the period from the beginning of the project until the middle of December. Therefore, the reduction of inspections in the products Total Joint, modifications in the sheets of inspection, increase in the quantities of the work orders and the standardization of the processes was very successful in the areas of production for work orders ≤ 100 pieces.

CONCLUSIONS

The PDCA Cycle is a tool that allows the management of processes with the purpose of continuously improving the objectives, eliminating opportunities to fail and redesigning processes if fuse necessary.

Since statistic is one of the pillars of this kind of methodology, through the use of tools it can organize data, measures the capacity, effectiveness and controls the variation of the processes, decreasing the downtime production. In the implementation of improvement projects, are involved from senior management to operational staff, generating a culture of leadership and motivation.

Organizations develop the PDCA cycle in process improvement planning by performing the following steps:

1. Detection of improvement areas.
2. Improvement actions.
3. Programming improvements.
4. Implementation of the improvement plan.
5. Monitoring and evaluation of the improvement plan.

PDCA Cycle could be considered as tool to support quality management system of all manufacturing industries of large productions, to develop a more advanced form and technical principles of management by processes, staff participation, decisions based on facts, and the customer focus, using statistical tools and improvement. The quantification of improvements obtained by implementing the PDCA Cycle, and the start a program of autonomous maintenance, can be done through the reduction of costs, taking the reduction on downtime and the decrease of defects s parameters.

Learning through practice is the best case scenario to present. The sources of learning are diverse, but we can focus the analysis on three of them: first, the meaning of the evaluation, or what we evaluate. On many occasions we invest a huge effort in the evaluation process but we do not develop improvement actions and systematize its design, implementation and monitoring to give way, more tad, to more ambitious actions once the methodology has been internalized.

Finally, and having verified the improvement in the evaluated processes, we can also analyze the key factors that have facilitated the achievement of those improvement objectives. Undoubtedly, they include the establishment of improvement objectives (defined following an appropriate methodology), the systematization of a series of actions for improvement, and very important, the follow-up of these actions. But we also need to take into account other key elements that in this case have been paramount: the involvement of the inspectors who make the improvements and the recognition by the institution through the various incentive systems. We have presented the results of three annuities and we will continue to study how

the results of the indicators evolve in subsequent years trusting that they will continue to pursue continuous improvement [10].

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