Workmanship Error at Assembly Line in a Medical Device Company

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Abstract *— In a Medical Device Company a production line had an increase of non-conformances in 2011. The category for the increase was workmanship error. These failures result in cost of poor quality due to quality holds. The Failure per Million is 205, the goal for the year is 180, and the objective is a 15% of reduction. These failures impact the company to comply with International Organization for standard (ISO) 13485. To be certified by ISO the manufacture shall demonstrate that investigations are made for each non conformance reported. If an increase is observed it is management responsibility to assure defects are attended and corrective and preventive actions will be generated. The methodology used to obtain a reliable production line was DMAIC (Define, Measure Analyze, Improve and Control). The projects mayor improvement is a new systematic visual aid procedure Process Picture Mapping which would be implemented further to the entire company.*

Key Terms *— DMAIC, PFMEA, Poka Yoke, PPM.*

INTRODUCTION

An increase in Non-Conformances for workmanship error was observed during the monitoring corrective action board meeting. These failures result in cost of poor quality (COPQ) which ends up as: quality holds inside the facility major consequences of inventory, rework, and double inspections. These failures impact the company to comply with International Organization for standard (ISO) 13485 [1]. ISO requires the company to have controls and data within the specifications which assure the product to comply with the standards. Being certified by ISO makes the company reliable, predictable where products can be distributed to customers with a confident level that the products are of high quality. The most common failures observed in the workmanship errors are: "Did not follow procedure"; "Lack of standardization and inconsistence during inspection". The Failure per Million is of 205, the goal for the year is of 180, the objective is a 15% of reduction. To improve this manufacturing line it was proposed to open a project that would be developed with the Methodology of DMAIC (Define, Measure, Analyze, Improve and Control). During the definition and execution of the project it was found that the process flow of the product, fixtures of the assembly line and procedures needed to be improved. It was proposed to implement several fixtures to ensure the standardization and new procedures that would assure the reader understand and have good guidance during execution. Opportunities found in the procedures were lack of visual aids and descriptions were not easy to follow. Also it was observed that many of the procedures had more than three pages and were written in English. This made the associate confused and induces them to assemble by memory. Process flow of the product was evaluated and changed where the handling and misplaced products would be reduced.

LITERATURE REVIEW

The research regarding human error was done under three different journals, in which training provided by Talsico's company regarding the science of human error and two other articles related to this failure [2]. The training from the company Talsico International of the science of human error was taken to better understand the reason human errors occur. This was done as a prevention of not making the same mistake when improving and implementing the changes for the manufacturing line. Human error is defined differently in each research document, but with similarity. Error Management Training defines human

error in three components: “Errors occur only in goal-oriented behavior; they imply the nonattainment of a goal; and they are potentially avoidable”.

Talsico defined human error as “An inappropriate action or response by a person resulting in an undesired outcome” [2].

In the other hand journal Human Error: A concept Analysis defined it separately as: Error is “an act, an assertion, or a belief that unintentionally deviates from what is correct, right or true the condition of having incorrect or false knowledge; the act or an instance of deviating from an accepted code of behavior, a mistake [3]. Combining the meaning of the word “human” with the word “error” leads to an examination of human error – characteristic of human beings that involve unintentional deviations from what is correct, right or true”. Journal Introductory Human Factors, Reliability, and Error concepts defined human error as, “a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency” [4].

Internet site Human Error and quality control in Medical Devices defined “Human error is a broad category that includes the clearly identifiable, easily diagnosable, and seemingly excusable mistakes we all make [5]. Error encompasses all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency”. Each document classifies the human error in different categories. Talsico has six categories of human error which are defined as the following: Learning Gap, Memory Gap, Inconsistency, Application, Omission and Decision. Each are defined as: Learning Gap- don’t know – lack still or knowledge, or insufficient understanding of consequence; Memory Gap – Know but don’t remember – unable to use skill or knowledge at time/situation required; Inconsistency – “Know” but variability in method/standard- inconsistent performance/results; application – know but applied incorrect action/ information – slips, wrong outcome, transportation errors; Omission – know but missed a step/ action/information/difference - missing information/step, used wrong item and Decision – wrong decision given situation/information – inappropriate decisions and/or behavior. Internet site categorizes in five different types of erroneous thinking as follows: Partialism- This occurs when the thinker observes problems through one perspective only; Adversary- This occurs when the thinker believes that because someone else is wrong, he should be right; Time Scale- This happens when the thinker sees a problem from a limited time frame; Initial Judgment- This occurs whenever the issue or problem is not considered objectively; Arrogance and Conceit- This occurs whenever the thinker believes that his or her solution is absolute and no better one exists. For journal human error and factor it states that after several attempts that have been made to classify human error, Miller and Swain adopted an outcome- oriented approach in which there are six types of errors, which are: Commission – adding or including something that should not be there; Omission- missing something out, for example, from a sequence of steps; Selection- incorrect choice from a range of options; sequence- incorrect serial positioning of actions or events; time- too late or too early with an action; qualitative- not performing an action properly. The factors that come in our mind while an investigation is being completed; was the person trained to perform the task; was the training effective; is the task easy to perform just as it is; are the instructions clear to repeat the task. Human error research has been carried out since the 1960’s maybe further back, where the man starting to investigate and understand that human error were caused by other factors and not necessary caused by the person achieving the task. Research in the documents mentioned before all have the same information regarding failures due to workmanship error and why do they often occur and not necessary should be classified as a workmanship error. There are classification describe as physiological factors which are: Stress – can be at work or in their home which bring to a day’s work; Noise; Ergonomic issues- poor light; uncomfortable in the stage of work; Human interaction; Circadian rhythm- “recall” memory best 6 am to midday. Most error-prone 4 am to 6 am;

Temperature- too cold; Nutrition- this can cause memory loss increase of failures. Also documents details that failures are cause due to latent facts such as: Design failures; inadequate fixtures; poor maintenance of procedures; poor operating procedures; poor housekeeping (5S); system goal incompatible; organizational failures; communication failures – poor feedback or none; inadequate training; other improper work tools; poor management; poor work layout. With all these factors we can conclude that human error can be caused due to a range of faults not necessary a human error but factors that make us err. It is observed by all documents that companies learn from their mistakes and see that mistakes are beneficial if the process cannot be atomized due to the complexity of the task mistakes will make you improve the process and reduce failures in the further that could result in death or 483/warning letters from the Food and Drug Administration (FDA). Human error and human factors classify errors as a learning tool where it is important to recognize that making mistakes and receiving the feedback is essential for human learning to occur.

PROBLEM STATEMENT

Failures of workmanship errors during the assembly line in a Medical Device, has an increase of 12% in Non-conformance. The impact of this is the following: Result in a customer complaint which could result as a severe injury or death to the customer; could impact to comply with certification of International Organization for standard (ISO) 1348; cost of poor quality (COPQ). The most common failures observed in the workmanship errors are: "Did not follow procedure"; "Lack of standardization and inconsistence during inspection". The objective is a 15% of reduction. When a non conformance is reported a quality hold is immediately placed, where the entire product manufactured with the non conformance is placed on hold until investigation, corrective and preventive actions are defined. This can cost a company millions of dollars, where a team of engineers, operators and managers are involved to define the problem. If the non conformance is confirmed a rework can be initiated or a product can be scrap if product cannot be reworked, another case can be that non conformance range of product affected has already been distributed and a recall needs to be generated. This project will benefit the company by maintaining the product in the market with a high quality aspect. Also with this reduction a major contribution will be assuring the ISO and Federal and Drug administration (FDA) certification.

METHODOLOGY

The Methodology to be used in order to accomplish the objective and goal of this project is Lean Six Sigma with the tool known as DMAIC [6]. This tool has a meaning in each letter which provides the guides of how to understand and begin a problem, develop, implement the corrective actions and sustain the implemented project. The DMAIC methodology is frequently used to root out and eliminate the causes of defects. The definition of each letter stands for D- Define – Define the overall problem that is being investigated; M – Measure – The problem to gather accurate and sufficient measurements and data; A – Analyze – The data to determine the root cause of any poor performance, determine whether the process can be improved or should be redesigned; I – Improve – The process once a solution is identified, it must be implemented and the results must be verified with independent data; C – Control – The solution, a verification of control must be implemented. A robust solution will be easier to keep in control than a qualitative one. First phase is Define: where tools such as a Project Charter, Brainstorming during a Kaizen and a SIPOC of the process. The Kaizen will be used to perform the barnstorming which will define better the project. The Brainstorming will gather all the ideas from the team members and/or solutions in a short time. This tool allows that all team members participate and eliminates any possibility of loss ends. Also it is discuss the way the data will be collected. How is this done, the team will review the problem definition, clarify the goal/ questions and provide relevant information. No criticize is allowed during this section of the project since all ideas can be the solution of any

problem. The Project Charter is a main attribute when starting a project; this will assist the team to identify the objectives and the scope of the project. Also all the critical project deliverables; state the customer and project stakeholders will be assigned. This will list the team roles and their responsibilities; create an organizational structure for the project; documents the overall implementation plan and any risks, issue and/or assumptions. The SIPOC tool will be used to understand the process as a Micro point of view. This is a snapshot that can capture information critical to the project and helps the team and sponsor agree on the scope. The second phase is Measure, this is where the data is gathered and verified. The data will be collected is gathered by the quality engineer where the Failure per million is calculated. All the failures reported by the manufacturing line are entered in the quality system Agile. The data will be filtered by process and to be confirmed workmanship error. The data will be presented in Pareto charts. The Pareto chart, which is the concept of 80/20 rule, this principal is that 20% of something always is responsible for the 80% of the results. The third phase is Analyze, which should enter once the data is collected and verified. In the Analyze phase is to study the Pareto charts. A Kaizen event will be performed, Kaizen stands for continuous improvement it comes from Japanese word that comes from change and correct. It is a system that involves every employee – even upper management. This concept is to make little changes on a regular basis. In this event the entire team will gather and analyze all the data. The data obtained will be analyzed during a Kaizen. Also the tool of Risk Assessment and process flow will be used. The Risk Assessment tool that will be used is the Process failure mode effect analysis "PFMEA". This PFMEA will identify the manufacturing line where each non conformance identified has a negative result to the customer and company. This tool identifies both company and customer and provides the probability of the defect happing. It also shows where are the gaps in the process, such as lack of procedures in the task, fixtures and/or validation. A process flow will be used to understand how the product is assembled in the manufacturing line and verify if the process requires any improvement. The fourth phase is Improve; tools to be used are Visual workplace, 5S and Poka Yoke [6]. Visual workplace methodology needs to be implemented in order to create procedures more focused in the employee's language. This is a lean manufacturing concept. The benefit of this tool is that it will improve workmanship error and safety issues. The tool helps employees to avoid wasting time by giving them the correct information and easier understanding. The visual workplace will be implemented with a concept from the training provided by the company called Talsico. The training was focused on Human Error reduction. Demonstrating why this will always occur and how visual aids help the employee to execute the task without making a mistake or at least reducing the possibility of occurring. The 5S program is usually a part of the visual workplace. This methodology provides visual aids and standardizes the process where every employee performs the same execution. The 5S stands for Sort (Clean up) – Though everything in each work area, keeps only what is necessary; Set in order (Organize) – Arrange and identify everything in a work area for most efficient and effective retrieval and return to its proper place; Shine (Regular cleaning) – Once the first two are established the cleaning process must be set to maintain the first two; Standardize (Simplify) – while learning the process update and modify the standards to make the process simpler and easier; Sustain – continue training and maintaining the standards. The 5S will not be fully implemented in this project but since the concept from Talsico is the standardization and the visual aid it is necessary to be mentioned. The Talsico program has visual aids that have to be used as standard in all the processes not only for this project and this manufacturing line but will be expanded to the entire company. This project will be the pilot for all the other areas. Also a tool to be used is the Poka Yoke. This is a Japanese term that means "fail-safing" a method of preventing errors by putting limits on how an operation can be performed in order to force the correct completion of the operation. This system involves any automatic device or method that either makes it impossible for an error to occur or makes the error immediately obvious once it has occurred. This topic is included in ISO 16949:2009;

quality management standard that contains particular requirements for the application of ISO 9001:2008 for automotive production and relevant service organizations. The standard suggests that organizations incorporate error-proofing methods into corrective action policies and implement a defined process for problem solving designed to identify and eliminate root causes. The Poka Yoke will be used by implementing equipment that will be electronic and one only way to be assembled. The fifth phase Control will be used with the validation of each implementation and the monitoring of the FPM data in every corrective action board meeting "CAB". The monitoring of the projects for three months will confirm that the projects were effective.

RESULTS AND DISCUSSION

The results obtained for this project was an 80% of reduction in workmanship error. This was accomplished by using the methodology of DMAIC. The first phase Define: was used with tools of Lean Six Sigma. The Kaizen was performed with duration of one week where the Define phase had to be completed and approved. The project statement and objectives were defined and documented in the project charter and approved by management. This document will reduce the risk of the project being cancelled due to lack of support or perceived value to the company. This documents the overall objectives of the project and helps manage the expectation. Refer to Table 1 that resumes' this document.

The project statement is the reduction of workmanship error. During the Kaizen the project Charter was presented to the team and Pareto Chart. The team evaluated the entire process and interviewed the associates. A flow chart of the actual process was created.

A Brainstorming was performed to better understand the faults most observed during the interviews. Also a SIPOC was generated for the overall process Macro point of view. Team roles were also defined knowing each one specifically their assignments. The project stake holders were identified to be the Plant Manager and Quality Manager for this project. Assumptions and Risks were discussed, where it was clarified that new training of Talsico had to be systematically implemented in the plant as a quality requirement for this new method be successful. Process Failure Measure Effect Analysis (PFMEA) would be upgraded with any changes due to this project where the risk and occurrence are calculated in this document.

Deliverables

- The entire team has to be trained with workmanship errors by a consultant for 2 weeks before starting the project.
- New procedures Process Picture Mapping (PPM) have to be updated.
- Analyze the equipment of the line and automatic the fixtures that need to be updated.
- All chance has to be validated and/or have passes by Change Control order before implemented, following companies procedures.

Constraints

- Training and no execution until finalizing the training.
- Approvals need to be accelerated.

Responsibilities

- Quality Manager: Will negotiate with the team members' bosses.
- Engineering technician and manufacturing engineer will study the fixtures and recommend new automatic ones. Will present the proposal and validate the change. Also, they will handle with the documentation.

The Quality Engineer will verify all the inspection in the line and control in procedures and perform a gap analysis. This task will be shared with the Manufacturing Engineer, Compliance Engineer, Line Leader, Human Resource and Manufacturing Technician. The validation documentation and lead will be the Quality Engineer.

Table 1
Project Charter

Project Charter	
Description	Reduction of workmanship errors due to tasks and inspections not performed as per applicable procedure (not following procedure), lack of process standardization related to fixtures issues and ambiguous procedure (missing specifications on the manufacturing procedures).
Scope	Improve procedures, process standardization
Goal & Project Statement	Reduce workmanship error by 15%
Business Results	With the reduction of defects, the product of the company will gain an increase more than 15% in profit
Team Members	Champion (Manager); Black Belt; Process owner, Process Team Members
Customer Benefits	Reduction of defects, reduction in delays
Project Plan/Timeline	Measure (1weeks), Analyze (1weeks), Improve (2 months) and Control (3 months)

During the Brainstorming it was brought to the attention the training method that is being held and that was a must to be verified. Benchmarking inside the plant with other units was the path to lead and understand if the others were having the same problems. This will be an open item after the project is completed. Trend analysis for non-conformance of Workmanship Error presented during the Kaizen was the data from 2009-11 (Figure 1). A draft of a new re-layout and/or process flow was discussed during this Kaizen (will be presented at the analysis phase and implementation phase).

Second phase is Measure, in this phase it was evaluated data trend from 2011. Data analyzed by the quality engineer and management staff during the board meetings was workmanship error, been the mayor defect for the ABC line in the past months. The data is measured 12 month rolling data. In 2011, FPM had in increase in May and August up to 205.

Data from the mayor offender is procedures not followed; lack of standardization and inconsistence during inspection. The reason of failures for the workmanship errors demonstrate that the 83% of the workmanship error were units not properly assembled. They were divided in two categories:

- Procedure not followed- which data demonstrates that this means inspections not performed, missing components, task not completed.
- Lack of process standardization which data categorized with this is related to fixtures not robust and operator has to verify the assembly, ambiguous procedure (missing specifications).

Third phase Analyze data from defines and measure, were studied in the kaizen. It was defined that analyzing the data of mayor contributions would reveal the solutions and task that required execution. Analyzing the data of workmanship error it was found the procedures not followed and lack of process standardization. An elephant chart was requested to compare years and previous month's behavior (Table 2). This tool is a way of tracking reoccurring non conformances. It was observed that three of the categories of workmanship error had increased in 2010 and all in 2011. A problem was occurring but had not been observed.

Table 2
Elephant Chart

ABC Workmanship Error top failures							
Year	Month	Not properly assembled	Missing label	Missing component	Ducumentation issues	Improper lubrication	Totals
2011	JAN	1	1	2	1	0	5
2011	FEB	2	2	0	1	1	6
2011	MAR	2	1	0	0	0	3
2011	APR	1	2	0	0	0	3
2011	MAY	7	3	4	2	3	19
2011	JUN	2	0	1	0	0	3
2011	JUL	0	0	1	1	0	2
2011	AUG	5	4	3	2	2	16
2011	SEP	1	1	1	1	0	4
2011	OCT	1	1	1	0	1	4
2011	NOV	N/A	N/A	N/A	N/A	N/A	0
2011	DEC	N/A	N/A	N/A	N/A	N/A	0
2009	ALL	10	10	8	5	5	
2010	ALL	15	10	7	8	4	44
2011	ALL	22	15	13	8	7	65

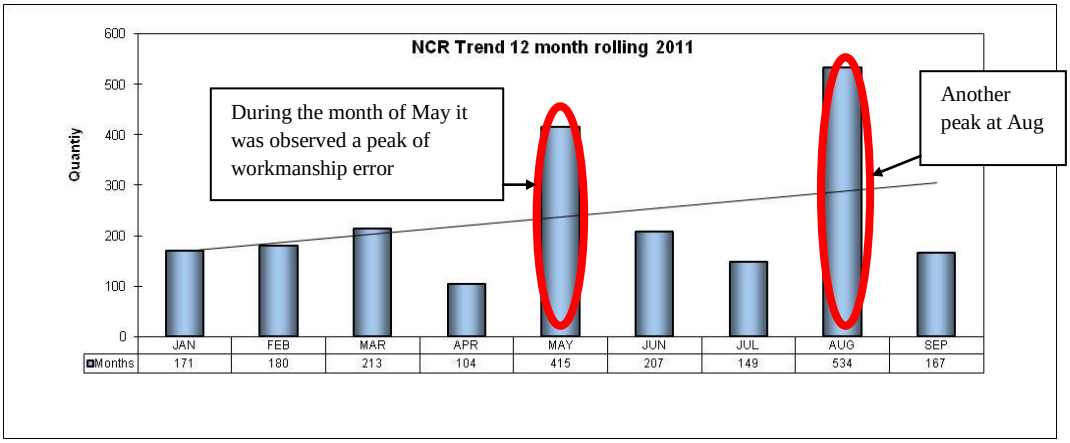

Figure 1
Workmanship Error for 12 Month Rolling

The training of the new systematic procedures and visual aids would start after the completion of the Kaizen. Many expectations in the training of this new system where three whole days the topics would relate of workmanship errors, why they occur, and how can the process prevent human errors. The Kaizen focused on the data and analyzing what was occurring during assembly. It was observed that all procedures were in English and did not have any pictures as visual aids. It was also brought that the fixtures were not optimum to be executing when an operator assembled a motor eccentric with the pneumatic fixture they would have to re-inspect since the fixture would not always align the assembly. It was recommended to validate a new automatic fixture. Also the assemblies for cyclohexanone were in a bottle the operator has the decision to wet as much or as less that he decided to complete the assembly of joining the components. Many other products in our facilities have automatic Ventrix which is programmed to give the amount of glue validated for the assembly The process flow of the product was evaluated and it was observed that each station had to inspect several task and also complete the task that was assigned in their station. It was recommended to eliminate all the inspection and only inspect the product for cosmetic non conformance and their assemblies. With this implemented the product would not have to go back and forward to the rework station and the reduction of defect due to handling issue could be reduce. This would also the probability of a product being reworked and not placed in the correct location. This is because the product could be rejected in any place during the assembly and if the product was almost complete it could go to a wrong station. The new station that will be implemented is for the 100% of visual inspection known as Total Quality Check (TQC). For this a visual aid will be placed for the operator to know how it is suppose to be assembled also the operator who assembles the unit will have this in there procedure. New proposed process flow re-layout was generated during the Kaizen and was approved to be implemented, refer to Figure 2.

Each task have several validation and change controls, it is responsibility of each team member to execute all as standard quality procedures.

All procedures were replaced with the new procedures format know as Process Picture Mapping (PPM). The format of the PPM is to begin from the top of the procedure. All the figures and brief explanation of what it means are located at top.

Left side is a flow chart of the assembly of that particular procedure. In the middle are the instructions of the assembly. On the right side are the most significant pictures of the task with a brief explanation. After the procedure is written next page is a picture of the tools that are used in this task, components Part Numbers and descriptions. After this the critical to quality pictures, are added, which is samples of wrong assemblies that have occurred, (refer to Figure 3).

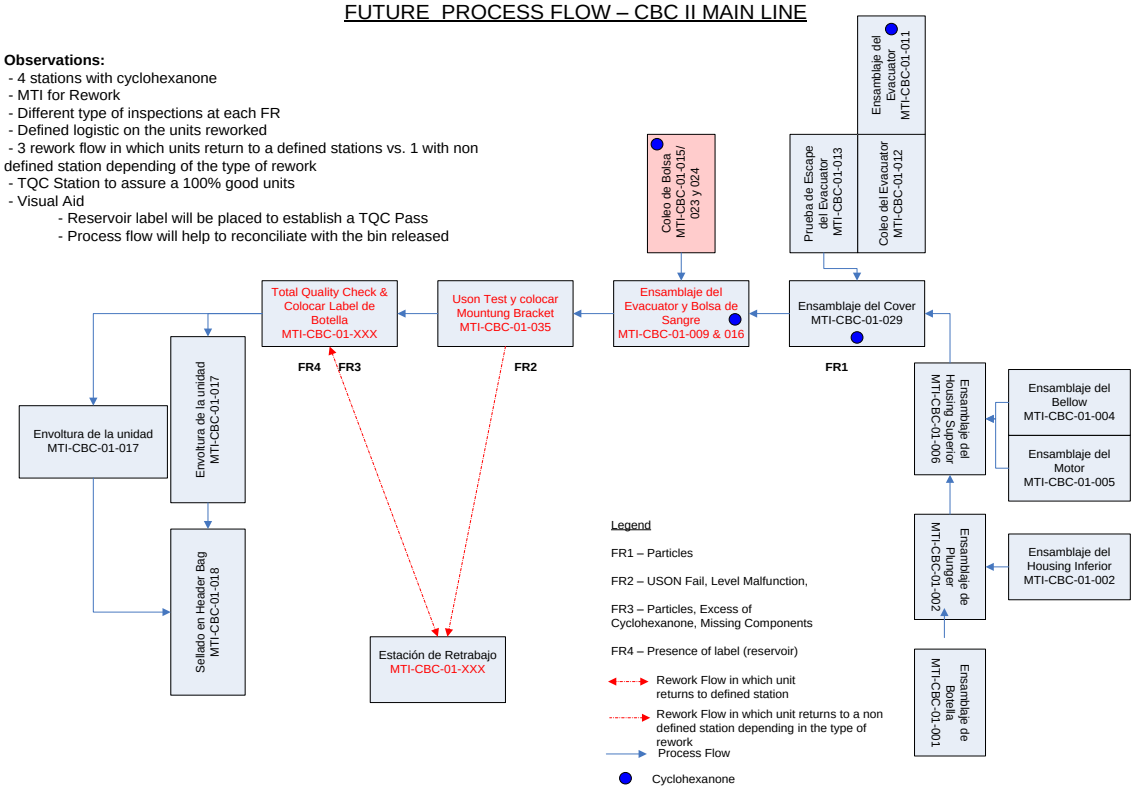

Figure 2

New Flow Chart for Process Flow

Figure 3

New Procedure PPM

Forth phase Implementation of all actions requested during the kaizen and workmanship error training. All procedures were changed to new format PPM. The re-layout would be implemented at the same time as the new procedures where the new station will be also included. Two new ventrex were implemented and full validation was required. The completion date was Jan 13, 2012. A new automatic fixture was also implemented, with the purpose to install properly the component which is assembled to the motor. It was considered a workmanship error due to the inspection after assembly. This fixture was designed as a Poka Yoke only one way to locate the component on the fixture. The new station of Total Quality Check will inspect if the label is correct and presence of all components. If they are not correctly assembled the product will be rework and return to this station. This is one of the implementation of the re-layout since a product use to arrive from any station. All projects were completed complying with the date established; (refer to Figure 4).

The fifth Phase is control, was to monitor effectiveness of all project milestones. A total of 3 months was established to be monitored in this stage. This was compared with the same data of 12 month rolling and the data of the 3 months within validation (refer to Figure 5). Each month during the Corrective Action Board meeting it was discussed the non-conformance of the product line most importantly the monitored project of workmanship error.

After the implementation during the 3 months monitoring only one NC for workmanship error was generated per month. This represented 80% of improvement. Demonstrating that all implementations where effectively and no changes would be required.

CONCLUSION

This project was defined by the problem statement where it was identified an increase of non-conformances, in a Medical Device line. The increase was of 12% in workmanship errors. The objective was to reduce this failure at a 15% comparing the acceptable upper limit and the accumulated data which demonstrated a better performance during the last two years resulting below the upper limit. The company decided to be more conservative and only calculate the object with historical data not taken in consideration all the changes within the project. A project was opened to reduce this failure complying with standard procedures of the company. The companies' procedures require immediate attendance to defects that demonstrate any tendency that could jeopardize the quality of the product and result in a customer complaint. This failure impacts the company to comply with International Organization for standard (ISO) 13485. The methodology to be applied to accomplish the objective was defined to be DMAIC. Each stage was completed conforming to the objective. Each phase of the project had to be meet expectations and had a significant role to accomplish the project. Tools such as Kaizen, Project harter, Brainstorming SIPOC, 5S, Poka Yoke and workmanship error training which implemented a new procedure format known as Process Picture Mapping (PPM), were used to develop an accurate project of corrective and preventive actions. A total of 3 months data was monitored, where results obtained were a reduction of 80% in workmanship error, exceeding the objective established. This project was a success and will be the pilot for the rest of the manufacturing lines in the company.

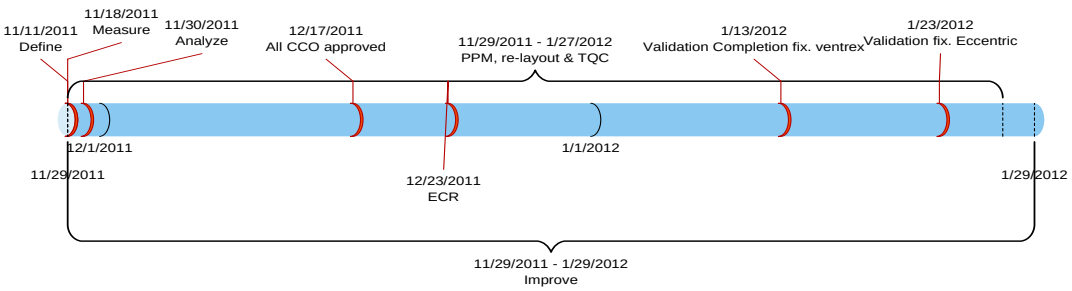

Figure 4

Timeline for Project Implementation Dates

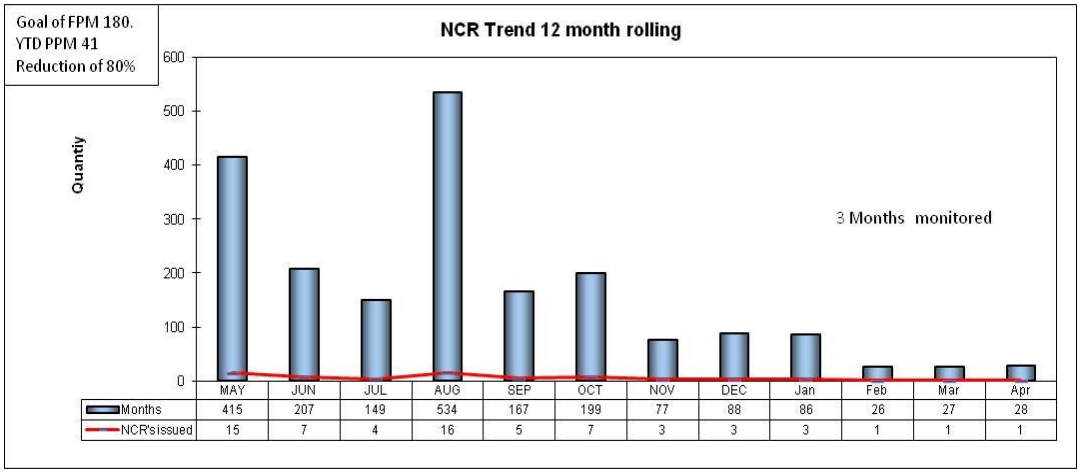

Figure 5

Improvement Graph for Three Months of Monitor

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