Medical Device Assembly Yield Improvement: Application of Quality Foundations

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Abstract *— Quality foundations application is not a new concept for medical device, manufacturing, and service industries. The key quality concepts have origins from the quality pioneers named as "gurus" Joseph Juran, Deming and Crosby. There are some key principles which many companies apply as part of project development and implementation. This article, as a final design project, presents the application of quality foundations on a yield improvement project for a catheter assembly line, where the customer survey scores were 48% out of 100%. The combination of voice of customer to achieve customer satisfaction, quality foundation tools application, and lean manufacturing concepts integration resulted on a yield improvement of 4%, and customer survey score of 60% due to the implementation of a new re-design UV fixture in order to reduce significantly the defect know such as coil damage.*

Keywords *— Catheter, DMAIC, VOC, Yield.*

INTRODUCTION

Industrial engineers worked with different systems where consistently are looking for efficiency, cost effectiveness and system optimization. Companies integrated different elements and tools such as lean manufacturing to achieve business goals and drive core metrics. MEDICAL MFG is a leading manufacturing contract company with more than 20 years on the market, who specializes in components and services used in interventional and minimally invasive products. They have several manufacturing sites which include Puerto Rico, United States, Costa Rica, and recent acquisition of New Business Ireland.

Research Description

Contract manufacturing benchmark demonstrates volatile turnover due to customer's high quality expectations, constant prices reduction, and service levels opportunities. The customers are focused on yearly revenues increase and push suppliers to demonstrate prices reduction initiatives consistently. This conducted design project will present the impact of the proper analysis of the voice of customer tools, and application of quality foundation tools resulted on the implementation of cost out project with the engagement of employees and customers. As part of the customer requirement, the area of focus is the yield improvement for a catheter assembly line.

MEDICAL MFG have the main focus of results oriented align with the strong performance of quality policy (Figure 1) considering manufacturing processes, good manufacturing procedures (GMPS) , customer service, and process improvement initiatives.

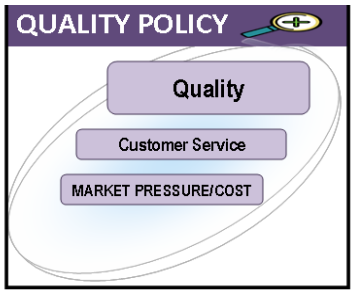

Figure 1
MEDICAL MFG Quality Policy

The project will be centered on the execution of a continuous improvement project guide by Juran's quality principles and foundation theories, which reinforce the importance of customers, key application of methods, performance excellence, leadership involvement and employee engagement.

Research Objective

The application of quality foundations on the implementation of yield improvement project have specific, measurable, attainable, result oriented, and time specific element focus on the accomplishment:

- Implement a yield improvement project on a catheter assembly line by June 2013 resulted on yield improvement of ~ 5% and $75,000 scrap reduction.
- Considered Voice of Customers (VOC) survey results and achieve at least 15% score improve by July 2013 due to the implementation of yield initiatives.
- Application of working teams and customer involvement during the project implementation to achieve project implementation.

Research Contributions

The project implementation will support a 5% yield improvement and $75,000 yearly cost reduction by the implementation of scrap reduction project for medical device assembly line in MEDICAL MFG, Costa Rica facilities. After the completion of this project, MEDICAL MFG will be attractive for actual key customer and new business opportunity due to the execution, customer active enrolment on cost reduction activity including kaizen event, where the participation includes employees and customer's key staff members.

MEDICAL MFG and acquisitions will be converting on the center of excellence with the demonstration of complete package on excellence in cost out programs, sustainable productivity considering lean tools application. Another key contribution of this yield project is the exposure of MEDICAL MFG team capabilities including design, development, project management, quality procedures compliance, validation among others.

The contract manufacturing works around a supply chain environment, where different cross functional departments work together to achieve the business sustainability. Quality, Engineering, Human Resources, Finances, Materials, Operations, and Safety departments align their strategies to achieve business targets including cost out, efficiency, services levels, and productivity in order to satisfy customer needs under the requirements of a particular scenario. The contract manufacturing environment present a scenario where customers are the owners of process, shop tooling, product intellectual property, and relationship depending of constant customer feedback about on time delivery levels, low complaints level, manufacturing execution, and yearly cost reduction initiatives.

MEDICAL MFG is working with the application of key quality foundations in order to develop a new internal strategy aligned with client's feedback quick response to achieve yield improvement and cost out initiatives for a key medical device company. The project implemented considered DMAIC methodology, kaizen tools application, quality tools, and principles consideration such as people engagement, working team's concept, Pareto tool analysis, and customer integrated partnership among others.

This conducted design project will present the impact of the proper analysis of the voice of customer tools, and application of quality foundation tools resulted on the implementation of cost out project with the engagement of employees and customers. As part of the customer requirement, the area of focus is the yield improvement for a catheter assembly line. Also, the project will be centered on the execution of a continuous improvement project guide by Juran's quality principles and foundation theories, which reinforce the importance of customers, key application of methods, performance excellence , leadership involvement and employee engagement.

Yield Improvement design project will be develop on Costa Rica's Medical MFG site, molding industry with a business strategy of the implementation of strong continuous improvement project, involving customers (internal and external). Medical MFG works under ISO13485:2003 standard and establishes a quality policy which promotes VOC and customer satisfaction through high quality standards, and cost effective products. The year 2013, was a year with over $500k in material miss due to catheter manufacturing line

scrap levels, corresponding to yield execution of 85%. This scrap levels resulted on key customer's dissatisfaction, due to additional transportation expenses and low service levels.

LITERATURE REVIEW

Business performance is impacted by different elements and there are different theories about the solution to sustain it, resulted on customer satisfaction improvement. Juran's, Crosby and Deming present three different points as part of quality foundations and customer satisfaction. This design project will include the common points; essentials to achieve outstanding quality results including: leadership, customer perception importance, people engagement, and continuous process improvement. The mentioned points are the principles on the implementation of the scrap reduction project.

Voice of Customer Measurable Tool

Customer satisfaction depends on customer perception including the two primary groups of customers [1]; external (outside of the manufacturing organization) and internal (inside the manufacturing organization). The dissatisfaction motivates customers to start a challenging process of periodical follow up calls, and start the interest of experimenting competitor's evaluation as a more attractive option. Considering satisfaction levels consequences, there is a useful VOC application commonly known as The American Customer Satisfaction Index.

The American Customer Satisfaction Index (ACSI): "Providing a customer satisfaction rating" is an independent national benchmark of customer satisfaction, which provide key information or economic indicator that measures the satisfaction of consumers across the United States (US) economy and present a clear scenario about the health of US economy. The results also are a key tool of competitiveness of individual firms and predicting future profitability. The ACSI interviews could be by a communication media or by direct interview and cover about 70,000 to 80,000 customers around the world (see Figure 2).

The main objective of the company resulted on the creation of reports with a metric or scores on a scale of 0 to 100 focuses on providing benefits at micro and macro level on a quarterly basis. Also the evaluators use key quality tools such as a Pareto, which is used to analyze the data deeply.

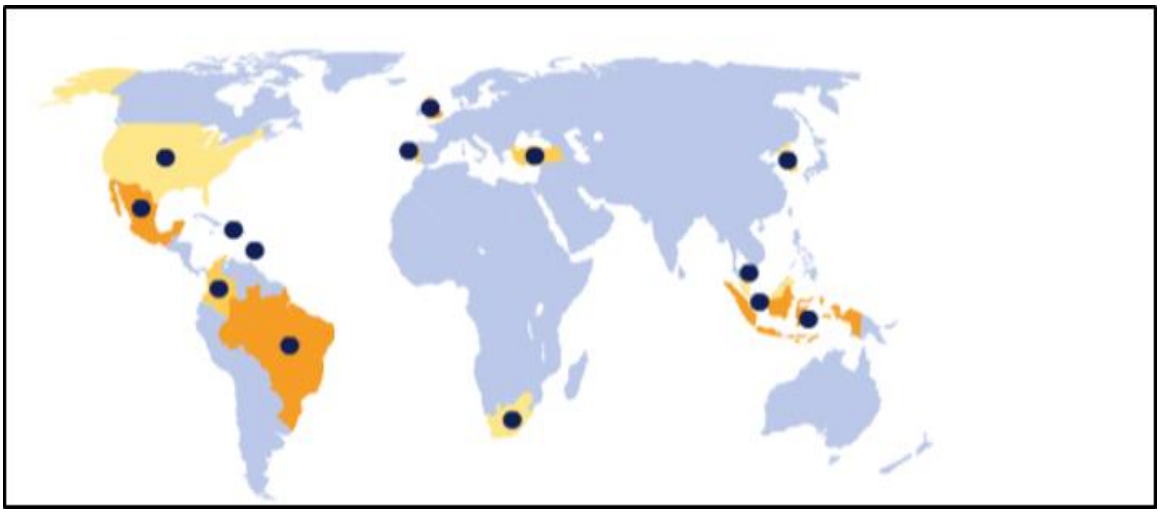

Figure 2
American Customer Satisfaction Index (ACSI) as a WorldWide Institution

Tools from Problem Definition

The accurate problem definition required the application of quality principles in order to going deeply into details. As an initial step, the data gathering is useful for problem definition because gives specific information about the problem. There are Quality Management pioneer, such as Dr. Joseph Juran, who recognized a universal principle for data gathering categorization, which he called the "vital few and trivial many" [2]. This principle established that 20 percent of something always is responsible for 80 percent of the results, and became known as Pareto's Principle or the 80/20 Rule.

The Pareto chart in a graphical tool that allows break big problems down into parts and identified which group has the biggest effect in the major problem. Applying this principle in the workplace means that a company will get the biggest payoff for our efforts if they focus on the “vital few” problems. Data collected and categorized, should pass through the application of root cause analysis in order to break the problem in key elements commonly known as the Ishikawa Diagram. Ishikawa diagrams are causal diagrams that show the causes of a specific event. Common uses of the Ishikawa diagram are product design and quality defect prevention, and to identify potential factors causing an overall effect. Causes are usually grouped into major categories drawn around a fish image to identify these sources of variation (see Figure 3).

METHODOLOGY

This project design followed the DMAIC Methodology. DMAIC [3] is an approach to problem-solving defined by Motorola as part of the Six Sigma management philosophy. It considers a proper structure and logistic sequence of five steps in order to achieve a certain process improvement. DMAIC includes define, measure, analyze, improve, and control (Figure 4).

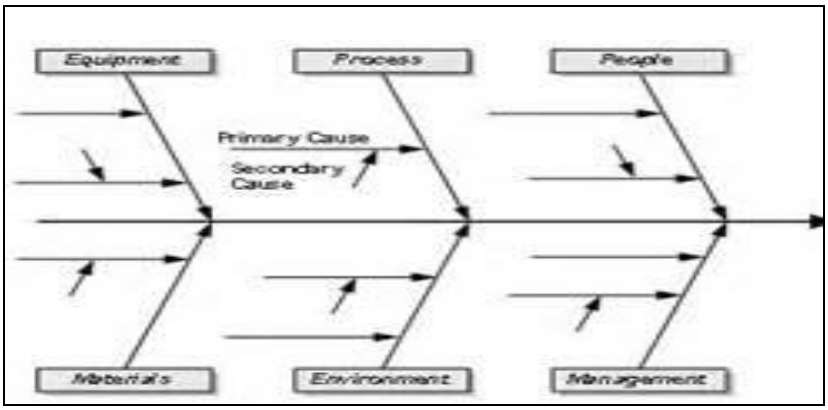

Figure 3
Fishbone Diagram Template

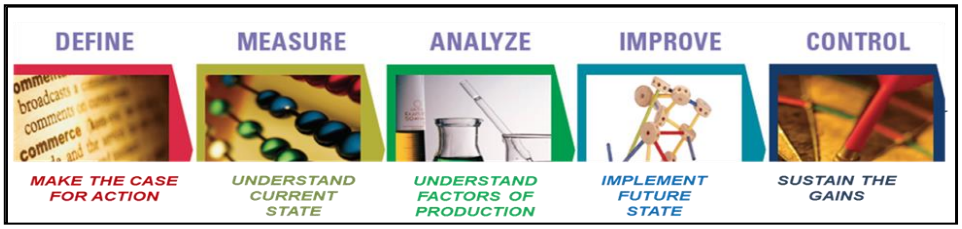

Figure 4
DMAIC Process

The yield improvement project follows the DMAIC methodology and began by establishing a project charter to identify why the project needed to be done, what are the goals, objectives and what will be the planning structure. A SIPOC (Suppliers, Inputs, Process, Outputs, and Customers) diagram, project Ghant Chart and VOC surveys were generated. In general, define phase includes the knowledge about who is the customer or end user, and requirements including a clear understanding of goals and the scope of the project including budget, time constraints, and deadlines.

Measure phase includes the accurate understand of the actual situation with data, study current process definition, including baseline data validation, and relevant data collection. SIPOC is a high-level picture of the process that depicts how the given process is servicing the customer.

The analyze phase helps to identify gaps between actual and goal performance, determining causes of those gaps, determine how process inputs affect outputs, and rank improvement opportunities. A key tool for the analyze step of the yield improvement project is the application of the 80-20 Pareto chart.

After analyze phase, the implementation phase takes place. In this phase the identified solutions, remediation plans, or corrective action and preventive action plans are incorporated to the process.

In control step there are important elements such as the generation of a detailed solution monitoring plan, observe implemented improvements for success, update plan records on a regular basis, and maintain a workable employee training routine, which must be addressed.

RESULTS AND DISCUSSION

Results of the DMAIC completed for this project is summarized below.

Define Phase

DMAIC framework provides a proper sequence for problems resolution under assignable causes. For that purpose a project charter was developed. The project charter is the planning team's concise statement of core goals, values, and intent in order to provide the ultimate policy direction for everything that comes next. Figure 5 presents each charter element in details for the application of yield improvement project in the catheter assembly line.

The project charter includes the project six sigma key phases and scheduling, considering feedback from customer and team members. The main objective of this design project is scrap reduction by $75k and 5% yield improvement due to the implementation of an engineering control worked with a design development team. The expected completion date is July 2013, including control elements such as standard work audit process.

Project Charter

Catheter Assembly line yield improvement project	**Project Leader**	Kenneth Rufino Nina
Dr. Rafael Nieves	**Project Sponsor**	Vention Medical
June 1, 2013	**Target Completion Date**	October 15,2013
From January to June 2012 ~26 units daily have been scrapped due to coil damage. The total scrap cost for this period is estimated at $250k. Averages of x units are rejected every day making this defect the second/third in the Pareto.	**Process**	VNUS – Covidien line
	Project scope	Catheter 60, 360 and 100 mm.
Reduce scrap $ by 75k and yield improvement by 5% due to the implementation of new fixtures	**Customer Benefit**	Reject rate reduction will impr and on time delivery. It will als associated risk with potential escapees from visual inspect production line
K. Rufino – Project leader. N. White – Design team leader Alfaro – Mfg engineer A. Perez – Quality rep. G. Sanabria- Mfg supervisor Vijay- Customer engineer	**Business Results**	✓ Yield improvement 5% ✓ Scrap Reduction by $75k

List the deliverables, supporting activities, resource requirements, and expected completion dates for each phase of the project.

Phases	Deliverables and Activities	Resource Requirements	Start Date	Finish Date	Comments
Define	Complete Project Charter, Is/Is Not, VOC	K. Rufino	April 2013	Mayo 2013	Done
Measure	Complete Process Map.	O. Alfaro	Mayo 2013	Mayo 2013	Done
Analyze	Root cause analysis and containment actions.	Team	Mayo2013	Mayo 2013	Done
Improve	Identify & implement solutions	K. Rufino	June 2013	June 2013	Done
Control	Implement control measures / plans	K. Rufino	July 2013	July 2013	Done

Figure 5
Project Charter

The SIPOC developed (Table 1) includes the following key elements in order to prioritize and identify focus areas of the process to be evaluated.

- Suppliers provide inputs to the process including patients, private entities, raw material producers, manufacturing team among others relevant in the assembly process.
- Inputs define the material, service, and/or information that are used by the process to produce the outputs of the catheter manufacturing. It includes process to

manufacture the catheter, procedures, quality inspections and, manufacturing facilities.

- Process is a defined sequence of activities of the manufacturing of catheters (see Figure 6). Catheter assembly required 20 continuous process steps including wire assembly, tip ball forming, testing, handle and, packaging.
- Outputs are the products, services, and/or information that are valuable to the customer including assembly part, packaging, and, key process.
- Customers are the users of final assembly products or services in the catheters manufacturing line not limited to surgery patients and production operators.

Table 1
SIPOC

Supplier	Input	Process	Output	Customer
Planning Department	Schedule	Catheter Assembly	Sequence of production	Manufacturing team
Wire Co	Raw Material		Assembly parts	Surgery patient
Operators	Mfg process		Assembly parts	Surgery patient
AEE CR	Electricity		Energy	Manufacturing team
Quality Rep	Inspection		Reject Bad parts	Manufacturing team
Henkel	Loctide		Catheter joints	Surgery patient
Excelta	Tools		Adjustment	Manufacturing team
Packaging Corp	Corrugate		Packaging materials	Surgery patient
Global Braid	Wire machine		Wind process	Manufacturing team
Omnicure Corp	UV curing		Joints curing process	Manufacturing team
Zona Metro	Building		Facilities	Manufacturing team
MEDICAL MFG	Quality process		Compliance	Manufacturing team
MEDICAL MFG	Pneumatic system		Functional leak test	Manufacturing team

Project planning is the key tool to track progress of project implementation and have the main objective achieves completion date on time. Project Schedule is a graphical representation of critical tasks (see Table 2), considering critical paths and supports or resources during the project phases.

Table 2
Project Schedule

UV cure- CD	Owner	Date	Comment
MPI review- line balance	Quality Manager	24-May	Complete
MPI to MC	Kenneth	29-May	Complete
Drawing fixture	Design team	29-May	Complete
Latch test	Kenneth	29-May	Complete
Install latches to all doors	Tool Room	3-Jun	Complete
VAL-423 review	Quality Manager	28-May	Complete
VAL-423 to MC	ME	29-May	Complete
MC release COV	Customer	8-Jul	Complete
Deviation	ME	17-Jul	Complete
30 samples to SJ	Kennetrh	17-Jul	Complete
EBR results	Customer	15-Jun	Complete
MPI redline	Team	15-Jun	Complete
COV release	Customer	15-Jun	Complete
Training- implementation	ME	15-Jun	Complete

Measure Phase

This phase includes the accurate understand of the actual situation with data, study current process definition, including baseline data validation, and relevant data collection. The development of a Process Diagram is very critical to understand process steps, and task order of the catheter manufacturing. The project will be execute on a 20 critical steps assembly process, including 6 man steps such as FEP, PET, Lumen, Tip, Handle, and MFG. Catheter assembly line is a continuous flow line to run any configuration. The actual scenario considers 2 main process; sub assembly and assembly and involve over to 100 direct labor employees which work 24 hours, 6 days per week.

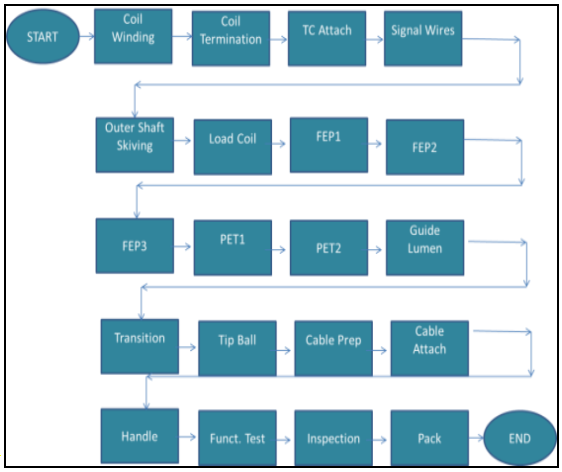

Figure 6
Process Flow Diagram

Considering VOC is an important element during any program development. It is part of the measure phase, to make sure that all data are properly collected and considered feedback from customers. Catheter yield improvement project is not the exception. Recent review with the customer shows several complaint types including on time delivery, freight cost due to expediting process, repetitive issues, and low yield performance. The catheter customer survey presents more relevance to quality and service aspects, but indicates disagreement in all aspects. The initial evaluation received a 49% grade (see Figure 7), which is not

the best score and call the attention to the managers to react promptly.

Voice of Customer Survey	
Customer:Catheter Assembly	
Quality 30%	Is the level of compliance at low level?
	Is the recurrence of the issues high?
	Is the organization follows GMPS?
	Is the sense of trust and profesionalism in the leaders of the organizatio
	Are the Change of management following procedures?
Cost 20%	Are the true manufacturing cost in control?
	Is the price competitive with the market?
	Do you feel empower with cost out, cost in iniciatives?
	Are the cost tracking process acurate?
	Are the KPI targets achieve?
Service 30%	Is the quick response good?
	Are the items on time delivered?
	Are the negociation process healthy?
	Are the KPI discuss periodically?
	Are the KPI allign with your objectives?
	Are the inventory levels accurate?
CI 20%	Is the process improvement significant?
	Are the process following VOC?
	Are the customer-supplier engagement strong?
	Are the root cause tools strongly alligned with your opportunities?
	Is the participation on kaizen events significatelly?
Grade	48%

Figure 7
VOC with ACSI Model

Run charts for rejects per day were developed (Figure 8). MEDICAL MFG catheter assembly line in Costa Rica facilities is losing close to $5000k in scrap. It represents an average of 170 units scrap per day. Most of the defects are detected on MFG station which is close to packaging station. Scrap dollars are affecting Costa Rica plant monthly profitability.

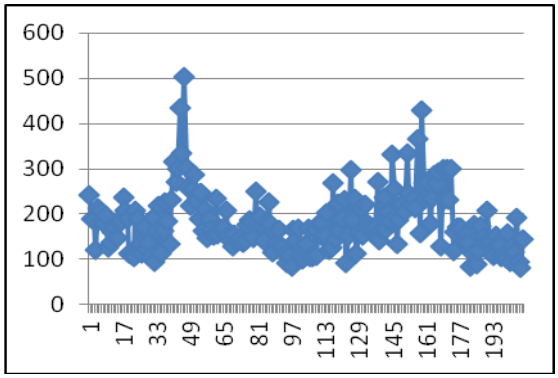

Figure 8
Run Chart Rejects per Day

Analyze Phase

A key tool for the analyze step of the yield improvement project is the application of the 80-20 Pareto chart. The Pareto of Yield defects per area and Yield defects per code gave a better idea to start the prioritization and areas of focus for the project. The first Pareto (Figure 9) shows that most of the defects come from MFG station, which is the final pack station. This data provide a better idea that most of the defects mainly come from common variables such as handling process and UV fixture because is present across all the stations.

Catheter assembly area included key areas which define main process. In this case the Pareto defined area where scrap % is mainly identified after key inspection process. It provides a guideline about the next steps, which is the second Pareto (see Figure 10) to prioritize defect with major impact. The presented chart shows that a 20% of total defects per year come from coil damage. Consider the offender contribution; the next step was the deep evaluation of the defect per day with the application of a quality foundation statistical tool known as run chart.

A year roll up was drawn on a trend chart with daily data and validate an average of 19 scrap units per day due to coil damage (see Figure 11).

A run chart is a line graph of data plotted over time. By collecting and charting data over time, the trends or patterns in the process can be found. In summary it shows how the process is running.

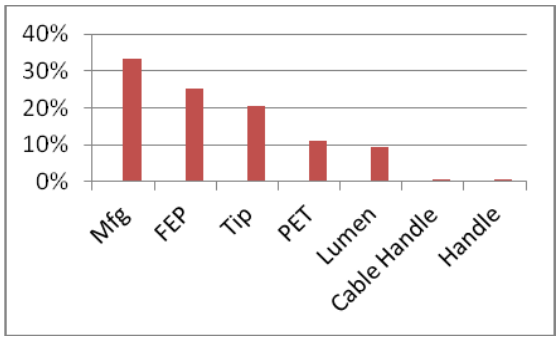

Figure 9
Pareto of Yearly Scrap % per Area

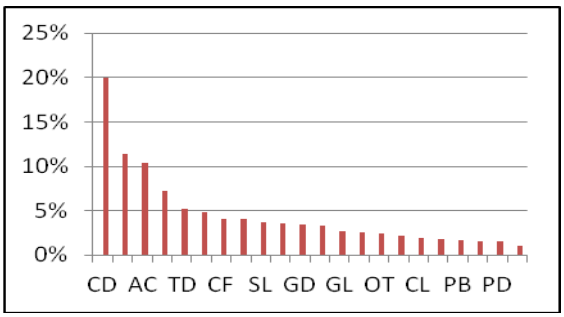

Figure 10
Pareto of Yearly Scrap % per Defect

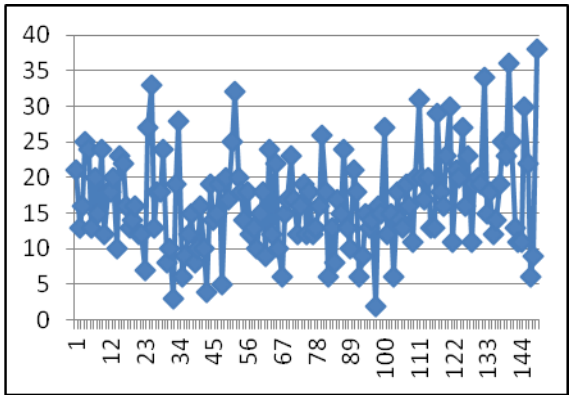

Figure 11
Coil Damage Defect per Day

After the identification of yield offender defect baseline, there an important next step as part of analyze phase. It's known as Fishbone Diagram or Cause and Effect Diagram (see Figure 12). It is a quality control tool that helps identify: root causes of problem uncover bottlenecks in your process and identify where and why a process isn't working.

For yield improvement project, the fishbone was developed to present the relationship between the elements which helps to determine the possible causes coil damage as a yield offender. The root causes tool considering important elements such as measurement criteria, labor factors, assembly methods, machines, and materials involve in the manufacturing of catheter. The selected main areas of focus will be the handling and machine aspects because are the common variables from station 1 to 20 and are variables not properly address.

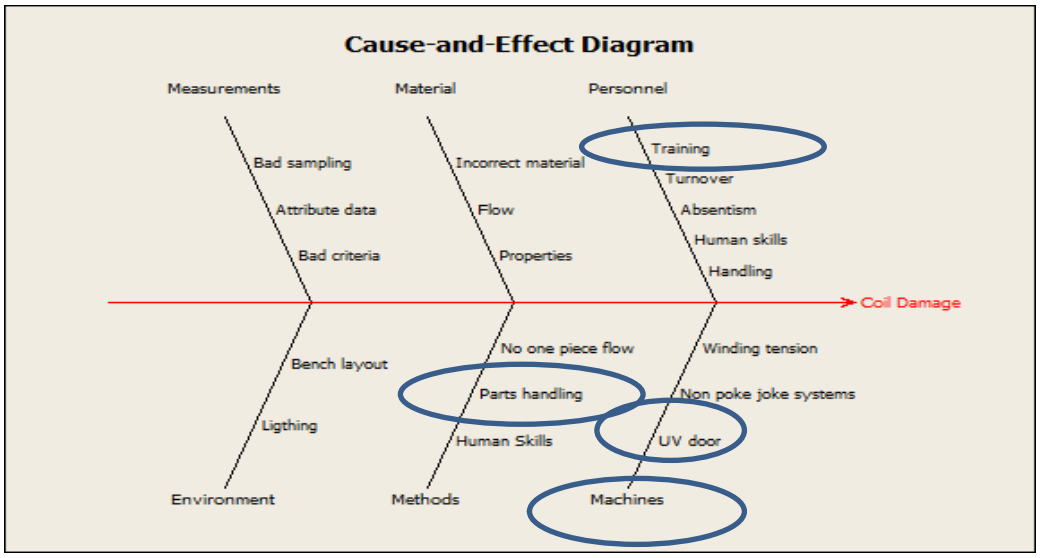

Figure 12
Coil Damage Fishbone

Analytical technique employed to reasonably ensure that potential causes of process failure, and the associated mechanisms, have been identified and addressed. This technique (PFMEA; Figure 13) was integrated on the yield improvement project in order to related potential failures with occurrence, determinability and severity. Also it served as audit tool or assessment about how well the process outputs meet the process input requirements.

Potential failure	Severity	Potencial cause	Occurrence	Det	RPN
Damage coil	1	Poor handling	1	1	1
	1	Contact with UV	1	1	2

Figure 13
PFMEA Evaluation

For the catheter assembly process there are a potential failure related with wire damage. A potential short circuit of the final assembly product is present in case that a damage product was assembled and sent to surgery. In terms of RPN,

the failure represents a low risk, including potential failures of UV operation, loading operation, poor handling among others. So, in summary this analysis gave a clear idea about the low risk of changes or improvements with the selected potential failure variables such as handling and UV fixture (Figure 14).

Figure 14
Coil Damage Representation

Yield Improvement project included the implementation of key initiatives and modifications resulted on significant yield improvements. One of the most significant implementations was the design of a new door which in concept is the implementation of hinge concept to avoid matching the catheter (Figure 15) instead slide door which open up down.

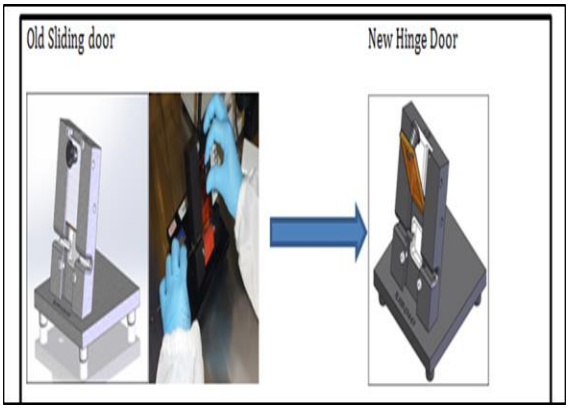

Figure 15
Before and After UV Door Concept

After UV door implementation on June 2013 the final yield improves from 86% to 90% (Figure 16). These results demonstrate strong contribution due to the mitigation on Coil Damage scrap defect. The project presents a PBP of 0.26 with $15,740 implementation cost and over $150,000 potential estimated benefits (Figure 17).

The new door follows the lean concept known as "poka joke". "Poka joke" is a Japanese term which means mistake proofing. A "poka-yoke" device is one that prevents incorrect parts from being made or assembled, or easily identifies a flaw or error. "Error-proofing" is a manufacturing technique of preventing errors by designing the manufacturing process, equipment, and tools so that an operation literally cannot be performed incorrectly.

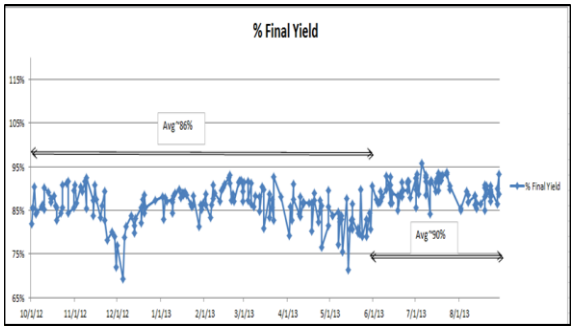

Figure 16
Final Yield with New Improvements

Implementation Cost	Cost
Design	$ 7,920.00
Development- assesment	$ 2,500.00
Expense-Fabrication	$ 2,240.00
Installation	$ 160.00
Validation cost	$ 920.00
Total cost of Implementation	$ 14,563.00
Implementation Benefit	**Cost**
Monthly Avg Scrap	750
Net Scrap cost	$ 31.00
Yearly benefit	$ 55,800.00
Paid Back Analisys	
PBP	0.26

Figure 17
Paid Back Analysis

After project implementation the reject rate was reduced from 29 units per day on average to 16 rejects units per hour due to the mentioned scrap code (Figure 18).

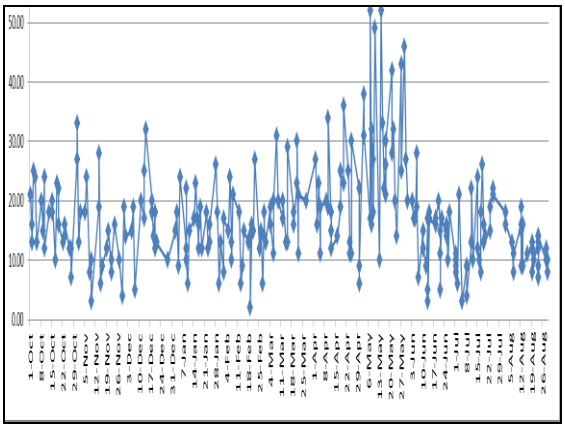

Figure 18
Average Defects Coil Damage per Day

Control Phase

For yield improvement project there is important quality foundation elements consideration such as standard work implementation. With this administrative control and checklist, the manufacturing team established clear expectations, audit process in order to sustain the gains. The implemented standard work (Figure 19) contains the most important indicators in the catheter assembly line including WIP policy to achieve proper material flow, inventory policy, and capacity study to orient operators properly and visually. In addition the formal document integrates elements such as manufacturing key process steps to achieve proper assembly order considering inspection levels and scrap alarms. Scrap Alarms, is a recently scrap visual management tool which represent the early warning under scrap levels out of control. For the catheter line 3 defects or more consecutively are call as abnormal condition and require immediate attention to avoid scrap propagation.

Everyone related to the catheter assembly process not limited to the engineers are involved on the catheter surgery application and the patient risk review meeting. This initiative increases the engagement and awareness in the production shop. A total of 3 shifts, 150 employees were train about catheter functions. Also KPI metrics, including scrap dollars, on time delivery are review with all employees. The main idea of Education meetings (Figure 20) is to share actual execution, financial results and reinforce product importance.

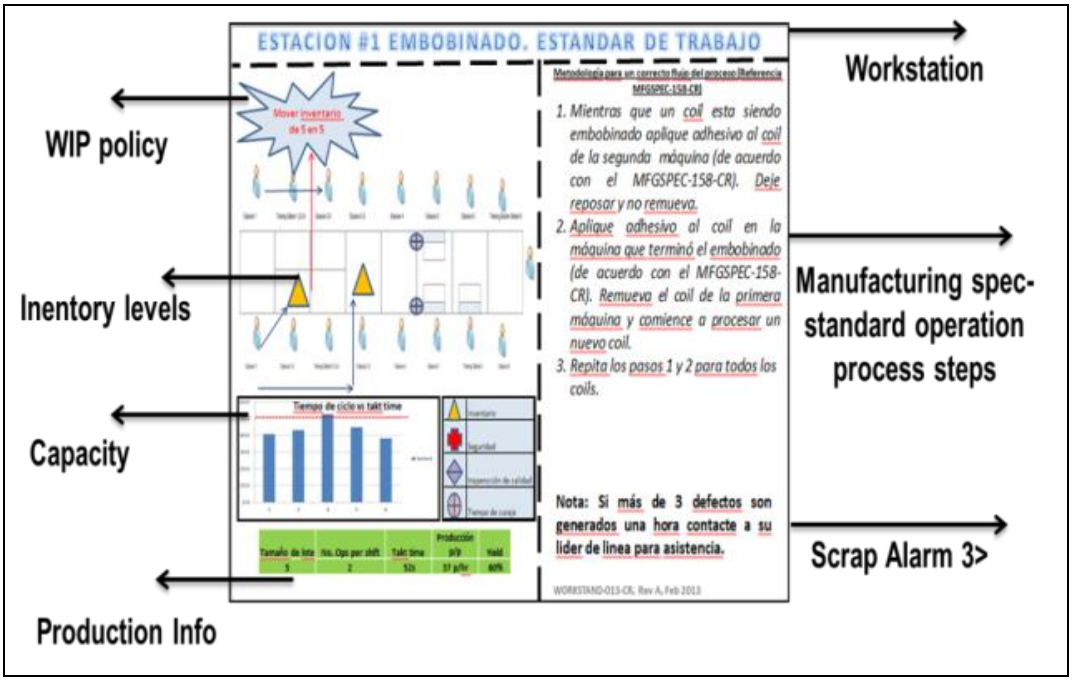

Figure 19
Standard Work Catheter Line

Figure 20
Education & KPI Review

Empowered employees who actively submit improvement suggestions, give an organization a competitive advantage in generating cost savings, improving productivity and increasing efficiencies when/if a program is properly implemented [4]. This initiative is a benchmark with US company sites where the operators provide suggestion their ideas to improve process. The idea suggests by the employee (Figure 21) will be recognized on a quarterly basis to achieve proper operator integration in day to day opportunities. This program will be launch mid-September with a yearly goal of .5 ideas per employee.

An important element to track progress is the application of customer survey after implementations. For yield project customer the score increase from 46% to 60% (Figure 22) due to satisfaction after yield project implementation and output. Yellow highlighted items represent the areas with significant changes, after project implementation.

Figure 21
Employee Suggestion Program

Voice of Customer Survey	
Customer:Catheter Assembly	
Quality 30%	Is the level of compliance at low level?
	Is the recurrence of the issues high?
	Is the organization follows GMPS?
	Is the sense of trust and profesionalism in the leaders of the organizatio
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Cost 20%	Are the true manufacturing cost in control?
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	Are the root cause tools strongly alligned with your opportunities?
	Is the participation on kaizen events significatelly?
Grade	60%

Figure 22
VOC with ACSI Model after Implementation

CONCLUSION

There are several key approaches as foundations to take in consideration in order to improve systems efficiency, discover problems, and solve business problems with sustainable solutions. One of the most important approaches is known such as customer satisfaction, which is focused on the utilization of systematic tools shared with customers to maximize business effectiveness. These methods present the opinion of the customer as the starting point including yield production repetitive line issues among others.

After the identification of repetitive issues and complaints, is necessary to the application of a well structure process application such as DMAIC in order to identify real problem definition, analyze statistical data focus on real root cause identification, and problem solving sustainability. The methodology considered the analysis of the historical data for a catheter assembly line which shows a big issue in terms of scrap loss close to $500,000 per year.

This strategy was integrated in the yearly business plan, considering project finance impact of $50k and was formally presented to the customer in order to demonstrate proper problem solving tools application which increase the confidence and customer satisfaction. In summary the implementation of the UV hinge door, the

application of administrative proper controls and with the well utilization of quality foundations impacted positively the external and internal customers. It means the implemented projected results on a positive impact to operational culture, employees' sense of ownership, customers' confidence-satisfaction, and business operational-finance results.

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