

## ***Right to Operate Training Metric Improvement***

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**Abstract** – *This research was focused on understanding why operators are unable to complete their trainings on time. Thus, impacting manufacturing support and increasing the effort of those operators that are qualified and ready for execution. Not having all operators within a team ready impacts the manufacturing process. The Lean methodology was implemented to reduce learning metrics of operators to be ready for manufacturing support. The DMAIC methodology provides structure and tools to improve a process by optimizing and sustaining business process. This research seeks to involve operators and make them part of the solutions.*

**Key Terms** – *Metrics, Operators, Shifts, Trainings.*

### **INTRODUCTION**

Businesses faces with important and rapid changes. This rapid change in the business environment forces the organizations to change their operations and structures. Adopting these changes fast and continues renewal of both employees and organizations help organizations reach the set goals and survive in the competitive market. To be accomplished in competition, companies need well-trained and well developed employees from front employees to the top level managers in the executive suite. Moreover, training process must gain continuity. Especially, in Pharmaceutical Industry, due to the fast and rapid changes and improvements concerning the regulations and procedures of Health, guidelines such as GMP (Good Manufacturing Practices), GLP (Good Laboratory Practices), GDP (Good Documentation Practices) etc. employees who are working should be trained and updated about the

current knowledge to increase the efficiency in the organization. To sum up, globalization, fast changes in regulations and procedures and technological shifts lead to changes even in organizations. In order to cope with these changes, companies need to train their employees.

### **Problem Statement**

Production process teams are having difficulties to complete training requirements needed to execute their assigned tasks. This situation results in increased efforts for those operators that comply with training requirements and thus are ready to operate. Leading to overtime and operators not able to support the operation. In the past, various six sigma projects were implemented to improve the training process for operators. Still today, we continue to have the same delay in having operators ready for operation. In the last 13 months, overdue training metrics median for Team 1 is (0.57%) and for Team 2 (0.87%). The goal is to decrease these percentages to have operators ready for operation support. The DMAIC methodology will be implemented to achieve this goal.

### **Research Description**

This project will pursue to understand from the operator's and Process Teams perspective gaps in the process. Operators are directly impacted and their input will lead this project to implement improvements to have operators ready for operation support and in compliance.

### **Research Objective**

This project aims to achieve a reduction in Team 1 and Team 2 overdue training requirement median 0.40%. This will reduce the increased

efforts from behave of already qualified operators, reduce overtime and contribute to have all operators within a team supporting production activities.

### **Research Contribution**

This project will incorporate operators and Process Teams to be part of the solutions and together identify improvement that will be sustainable. Also make management aware that they are essential for sustaining the improvements.

## **LITERATURE REVIEW**

The origin of 'lean' manufacturing dates back to 1950 when a young Japanese engineer named Eiji Toyoda spent three months studying Ford's Rouge plant in Detroit. Mr Toyoda studied Ford's methods and considered ways in which to improve them. He did that by keeping a keen eye open for waste, as any kind of wasted motion, effort, or materials [1]. A basic principle of the Toyoda method, and therefore of 'lean' manufacturing, is to eliminate activities that do not add value for the end user of a product or service. Another is to look for and improve the process continually.

The push towards lean manufacturing originates from the Toyota Production System which is often referred to as Just in Time (JIT) Production. The Toyota Company became successful after World War 2 when Japanese factory owners adopted a number of American production and quality techniques [1]. The manufacturing techniques of Henry Ford and the Statistical Quality Control ideas of Edwards Deming became the foundation of Toyota's production process.

Unlike the American automotive industry, Toyota encouraged employees to be a part of the production process. The company introduced quality circles, which was a group of workers who meet to discuss workplace improvement. Quality circle members make presentations to management with regarding the quality of production.

The developments made by Toyota were adopted by other Japanese manufacturers but none

were as successful. In the 1980s, American companies began to adopt some of the processes developed by Toyota and gave these names such as Continuous Flow Manufacturing (CFM), World Class Manufacturing (WCM), and Stockless Production.

Organizations face rising costs and increasing competition every day. Lean Six Sigma allows you to combat these problems and grow your business.

DMAIC is a data driven improvement cycle designed to be applied to business processes to find flaws or inefficiencies – particularly resulting in output defects – and to combat them. The goal of employing DMAIC is to improve, optimize, or stabilize existing processes.

Process is the focal point of DMAIC. The methodology seeks to improve the quality of a product or service by concentrating not on the output but on the process that created the output. The idea is that concentrating on processes leads to more effective and permanent solutions [2].

DMAIC is used by a project team that is attempting to improve an existing process. DMAIC provides structure because each phase of the process contains tasks and tools that will lead the team to find an eventual solution [2]. While DMAIC may be sequential, it is not strictly linear. The process encourages project teams to backtrack to previous steps if more information is needed.

### **DMAIC Methodology**

DMAIC is a structured problem-solving methodology widely used in business. The acronym for the five phases of Six Sigma improvement are Define, Measure, Analyze, Improve and Control. DMAIC refers to a data-driven improvement cycle used for improving, optimizing and stabilizing business processes and designs. The DMAIC improvement cycle is the core tool used to drive Six Sigma projects. All phases are required and completed in sequential order. (See Figure 1)

- Define Phase: Define who the customer are, what their requirements are for the products or services, and what their expectations are. The

project boundaries is define. In this phase the Project Charter, Project Plan, Communication Plan and Risk Analysis are developed. We map the process to understand the flow [2].

- Measure Phase: Develop a data collection plan for the process, collect and measure data from many sources to determine types of defects and metrics. Compare data collected to customer survey results.
- Analyze Phase: The data collected is analyze to determine root causes of defects and opportunities for improvements. Gaps are identified between current performance and goal performance, also help identify the sources of variation and prioritize opportunities to improve. Tools are used to investigate root causes and quantify the relationship between inputs (X) and output of interest (Y).
- Improve Phase: The target process by designing creative solutions to fix and prevent future occurrences. In the improve phase, innovate solutions are created to develop and deploy the implementation plan.
- Control Phase: The phase of control help to maintain and improve the new process implemented. This help to prevent reverting to the “old way”. This phase require the development, documentation and the implementation of an ongoing monitoring plan.



Figure 1  
DMAIC Methodology

## PROJECT METHODOLOGY

A systematic approach will be implemented as a methodology to achieve the goals of the project. The purpose is to understand from the operator’s and process team perspective gaps in the process. To identify improvement to achieve a reduction in overdue training requirement, reduce the increased efforts from behave of already qualified operators and increase the support for the manufacturing process.

In the Define phase the following tools will be used:

- Project Charter
- Risk Assessment
- Communication Plan
- SIPOC
- VOC – Survey and Focus Group
- GEMBA

In the Measure phase the following tools will be used:

- Value Stream Map creation
- Metrics generation

For the Analyze, Improve and Control phase tools to be used will be determined during the project process according to previous step results.

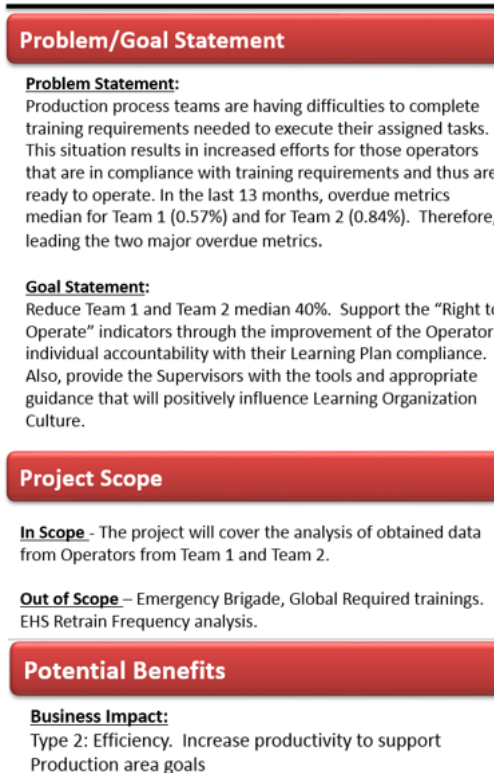
## RESULTS AND DISCUSSION

The results and tools obtained through the five phases of the DMAIC methodology follows.

### Define Results

As part of the define phase the Project Charter was created covering the problem statement, business impact, goals, scope, timeline and the team was defined. Since previous related projects were done with little or no representation from the production area, this project will have all members from the production area, being all operators and one from the training department. This charter was presented during the team launch and it will be revisit as the project advances to modify as needed. See Figure 2.

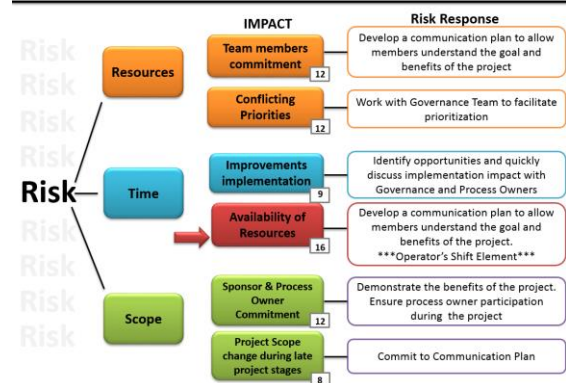
## Project Charter



**Figure 2**  
**Project Charter**

A risk assessment evaluation was performed to identify and bring potential threats or opportunities to the project to the attention of the project team. This document is important thus this allows to avoid management by crisis and prevent surprises. In this case, since most of the team members are from the production area they may not be able to participate of all meetings and activities due to area priorities and the shift element. Nevertheless, this is a risk we want to take. Their participation is key to identify gaps in the process and be able to find solutions. During the Team Launch the production management was addressed to have their commitment and allow operators to participate and the benefits this project will deliver. The commitment of the Sponsor and Process Owner is also important to achieve each of the DMAIC phases with success. They are also key to influence, achieve changes thru management and for the sustainability of the improvements. See Figure 3.

## Risk Assessment



**Figure 3**  
**Risk Assessment**

The communication plan is a strategy for communicating project related information to appropriate recipients. The key elements identified are the audience, media, topic, owner and frequency of the communications. Allowing a structural communication plan and commitment from the participants. See Figure 4.

## Communication Plan

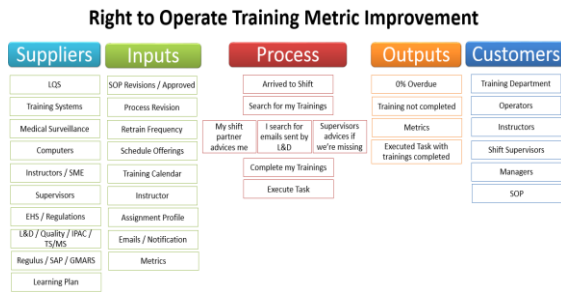
Audience	Communication Topic	Owner	Media	Frequency
Black Belt	<ul style="list-style-type: none"> <li>Project status</li> <li>Results / Achievements</li> <li>Barriers</li> </ul>	Magaly Peña	1:1 Meetings	Every Week Monday
Sponsor	<ul style="list-style-type: none"> <li>Project issues</li> <li>Project status</li> <li>Project risk</li> <li>Project schedule</li> <li>Barriers</li> </ul>	Magaly Peña	1:1 Meetings / Meeting Minutes / Emails / Tollgates	Every two weeks or as needed
Team members	<ul style="list-style-type: none"> <li>Pre-work progress</li> <li>Project status</li> <li>Next steps</li> <li>DMAIC tools</li> </ul>	All team members	Project Meetings / Meetings Minutes / Action List / Emails / Voice mails	Twice/three a month / 8:00am - 11:0am
Production Flow Staff	<ul style="list-style-type: none"> <li>Tollgate</li> </ul>	Magaly Peña	Presentation	As per project plan
Six Sigma Staff or Continuous Improvements Lead Team	<ul style="list-style-type: none"> <li>Project Status</li> </ul>	Magaly Peña	Presentation	As required

**Figure 4**  
**Communication Plan**

To gather data from the operators, basic elements of the process and understand the current process various tools were used as for the SIPOC, Focus Group, Survey and a GEMBA.

The SIPOC diagram identifies basic elements of the process (boundaries, supplier inputs, process inputs, steps, customers and outputs). This diagram captures a high level view of targeted operations. It helps in translating customer requirements into output requirements and identifying related key process output variables. From the process element we can see that operators do not access their

learning plan system to monitor the trainings they must complete. As a result of the diagram various metrics opportunities arise to be evaluated in the measure phase. See Figure 5.



**Figure 5**  
**SIPOC**

A precise understanding of exactly what the customers' wants is essential to identifying the defects. Customers' requirements are gathered, sorted, analyzed and expressed as critical to Quality Characteristics or CTQC's. These are the characteristics that really drive customer satisfaction. Focus groups with operators and another with only shift supervisors was scheduled. From the information gathered, operators and shift supervisors identified areas of opportunities as for:

- Production Time availability – It's difficult to take off the gowning and leave the process area for a 10-15mins training. Too many EHS trainings repetitions of things they do very day. Too many instructor led trainings assigned to handle vs their availability. Manufacturing is dynamic and it's sometimes difficult to predict if they will be able to assist to a coordinated training for them.
- Visibility – they need easy visibility of training offerings.
- Equipment availability – they need more computers
- Instructor availability – they need flexibility from behalf of instructors as they work a 24/7 shifts. Not sufficient instructors.
- Training completion expectations – No clear instructions on how to qualify an operator, no support for them when confronting difficulties with instructor availability.

- Others – No training sessions during night shifts. Little time for training completion before an Operating Standard Procedure (SOP) goes effective, its due date. They need prioritization in week day coordination, as they compete with non-shift employees.

A survey was designed to obtain answers that will meet the projects objectives. The survey was provided to all operators from Team 1 and Team 2. This method is efficient to gather considerable amounts of information from 88 operators. See Figure 6.

Questions	Results
<i>When you arrive to the shift, do you access your learning plan system within the first 2hrs of the shift?</i>	33%_Yes 67%_No
<i>Normally, at what time do you access your learning plan system?</i>	29%_6am-9:30am 49%_Other, when the area allows it.
<i>When is it convenient to complete trainings?</i>	47%_Night Shift 37%_Day Shift 35%_Weekends
<i>Is it easy to complete your instructor led trainings?</i>	20%_Yes 80%_No
<i>Is it easy to complete your self-study trainings?</i>	75%_Yes 25%_No
<i>Do you have access to computers to complete your trainings?</i>	47%_Yes 53%_No
<i>In what priority do you see training?</i>	25%_Critical 18%_Medium Priority 32%_Is part of what I have to do 25%_I do them if I have time

**Figure 6**  
**Survey Results**

To understand the process it was necessary to visit the area. For this activity, the Gemba Tool was implemented. Gemba is Japanese for 'the place where the event happens'. It consists of going to the process, seeing things from the customer's point of view, and asking people how this can be done better. The Gemba activity was schedule, see Figure 7.

Gemba Activity	
Area	Team 2
Date	XXXXX
Start Time	5:40 AM
End Time	10:40 AM

Figure 7  
Gemba Tool

From the observations and data collected, the following facts was resumed:

- 6 Operators in the area from 8
- 2 Operators are not qualified
- 1 new operator entered the learning plan system
- Observed area to be busy
- 5 hrs of observation

With all the data gathered, we are ready to move to the measure phase.

### Measure Results

The data collected in the Define Phase will be measured to determine types of defects and metrics. The data will be compared to the one collected in the operator's survey results.

An overdue metric was developed to determine how many operators go overdue each month. The study was done with data from 7 months from the 88 operators. As a result, we found 21 operators overdue in 3 or more trainings, representing 24% of the operators. See Figure 8.

### Overdue Metric Operator's Individual Performance

Statistics  
Observations: 530  
# Employees: 88  
Length: 7 months



Figure 8  
Overdue Metric Pie Chart

Operators learning plan was analyzed to understand how many more instructor led trainings they had versus self-studies. The results reveal that there was not a significant difference in percentage, Team 1 (51%-IL, 49%-SS) and Team 2 (54%-IL, 46%-SS). See Figure 9.

## Operator's Learning Plan

### Average of Total Trainings Assigned to a Operator by Area

	IL	SS	Total Items Assigned
Team 1	137	131	268
Team 2	126	109	235

Figure 9  
Total Trainings Assigned to Operators

The monthly training load for Operators was measured. The quantity of trainings ranged from 5 to 11 per month. Operators work an average of 174 hrs per month. These trainings represent from 3 to 6 hrs per month. See Figure 10.

### Trainings Completed per Month

#### Average of Trainings Completed by Operator per Month by Area

Teams	Average of Completed Trainings/ Month/Operator						
	1	2	3	4	5	6	7
Team 1	5	6	5	6	6	8	6
Team 2	7	9	6	5	11	9	8

Figure 10  
Trainings Completed per Month

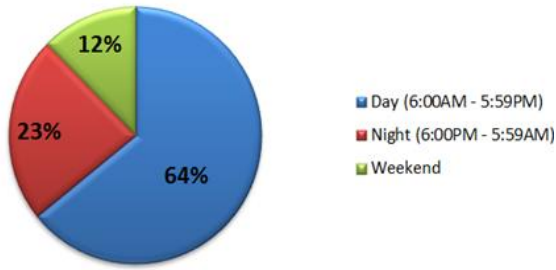
Training completion distribution was measured as for Day, Night or Weekend. The pie chart shows that 64% of the trainings are completed during the Day Shift. See Figures 11 and 12.

Observations: 5058 Items Completed  
# Employees: 88  
Length: 7 months

Shift Tendency	Total Items Completed	IL	SS
Day (6:00AM - 5:59PM)	3245	2000	1245
Night (6:00PM - 5:59AM)	1188	498	690
Weekend	625	150	475
<b>Total Items Completed</b>	<b>5058</b>	<b>2648</b>	<b>2410</b>

Figure 11  
Training Completion Distribution

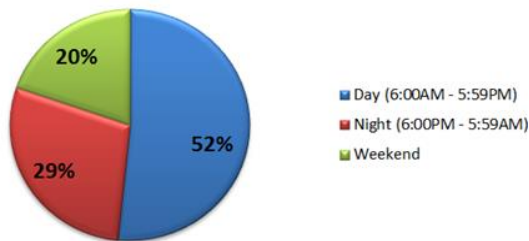
## Training Completion Distribution



**Figure 12**  
Training Completion Distribution

Then we measured the self-studies, these are training that can be completed in their computers at any time. The pie chart shows that 52% of self-studies are completed during the Day Shift. See Figure 13.

## Self-Study Completion Distribution



**Figure 13**  
Training Completion Distribution

The facts are that more trainings are completed during the busy day shift. There's an element during the Day Shift that is not present during night/weekend shift. The 1,245 hrs of self-studies during the day shift can be distributed differently.

A quick win was completed in this process. The control rooms were visited to count how many computers are available. It was found that in Team 1 had 2 and Team 2 had 1. This gap was completed during the measure phase and now each team has 5 computers available for the 11 operators in each group.

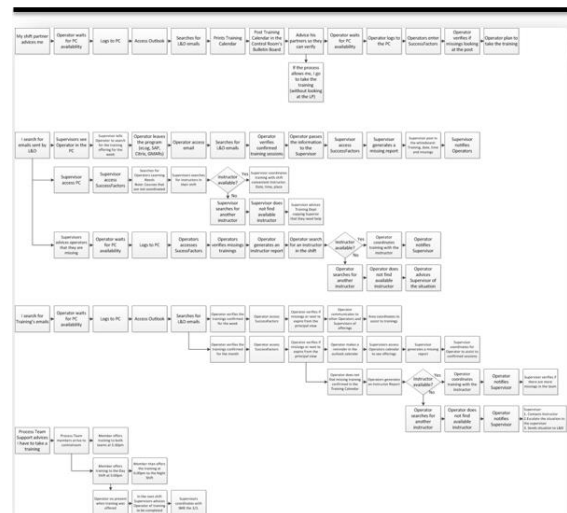
Lastly, a Value Stream Map was created to understand the current process flow by the manufacturing operators. The Findings were:

- 6 different ways Operators know they have a training missing

- Some operators complete training without verifying if they are missing. If someone goes to complete a training they go too without verifying their learning plan to see if they are missing.
- Some operators rely on supervisors for their learning plan needs.
- Most operators do not access their learning plan system as a first option. They depend on others to notify them they have a training to complete.
- Operators see themselves out of this process, they think they are not directly responsible of completing their trainings.

An illustration of the Value Stream Map is included in Figure 14.

## Value Stream Map



**Figure 14**  
Value Stream Map

## Analyze Results

In the analyze phase the value stream map and metrics were analyzed. It was confirmed that operators complete most of their trainings during the Day shift, even self-studies. The triggers are training department, management follow-ups and instructor going to the control rooms to train operators to be able to put their SOP effective. There's much less effort when the trainings are offered in the control room from behavior of the

operator and instructor. Operators rely on follow-up to complete their trainings. Operators have fairly an equal amount of instructor led and self-study trainings assigned. An average of 30 operators of the 88 complete their trainings on time, having the same requirement assigned.

A cause and effect diagram was developed to identify all of the contributing root causes likely to be causing a problem. The finding were:

- Opportunities for supervisors to plan production schedule activities integrating training offerings.
- The manufacturing area is demanding, too many interruptions in the control room from different service areas requesting information from the process.
- Insufficient instructor for safety trainings
- Training documents are not available for the instructor nor operator. Execution training documents are controlled and only accessed by training development. If the opportunity to provide a training arises in the night or weekend shift, they will have to wait until their next day shift to receive the training documents. This causes a delay in the operator's qualification completion process.
- No sufficient time for some training completions. Training owners want to comply with their responsibility of placing a training effective without taking into consideration that the audience needs time to complete the training. This has a negative impact in the learning plan of the operator and creates a burden for those operators that are not trained in the SOP and will not be able to execute. This also has an impact in the metrics.
- At this point operators still see themselves out of this process. They perceive they are not directly accountable for their trainings.
- Since there are no consequences training is not part of their priorities.

An illustration of the Value Stream Map is included in Figure 15.

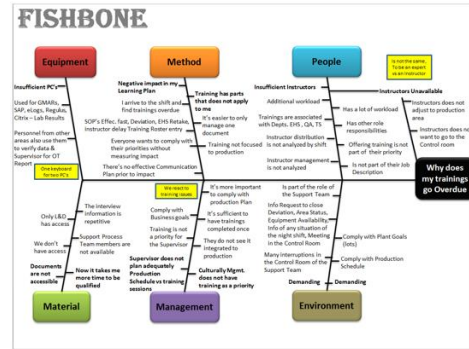


Figure 15 Cause and Effect Diagram

An exercise was done with the team members to identify the reasons their trainings goes overdue. A total of 32 casual factors were identified. They were organized using an Affinity Diagram. All casual factors were grouped into 8 categories. See Figure 16.

## Affinity Diagram Results

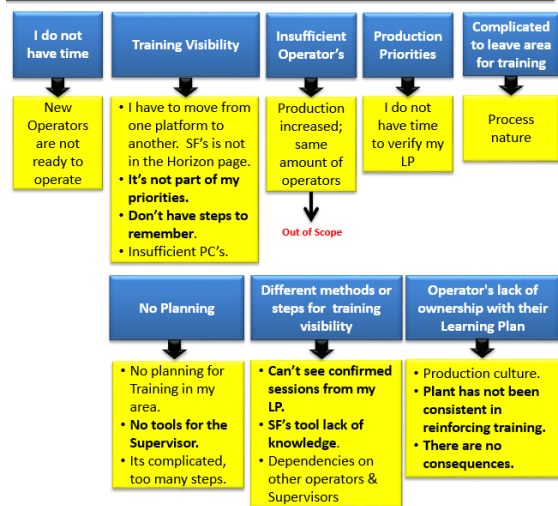


Figure 16 Affinity Diagram

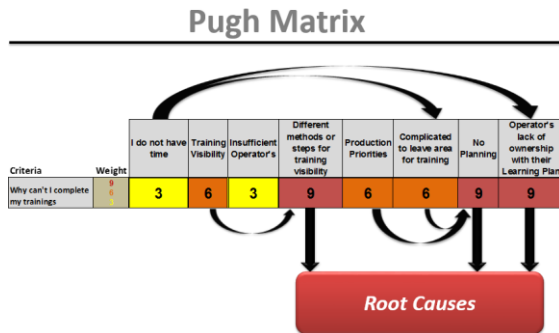
To narrow down the 8 categories a Pugh Matrix tool was used. The Pugh matrix is a decision-making tool to formally compare concepts (process, services, and products) based on customer needs and functional criteria. This tool helps us identify strengths and weaknesses for potential solutions. From the Pugh Matrix we identified 3 major root causes:

- Different methods or steps for training visibility.



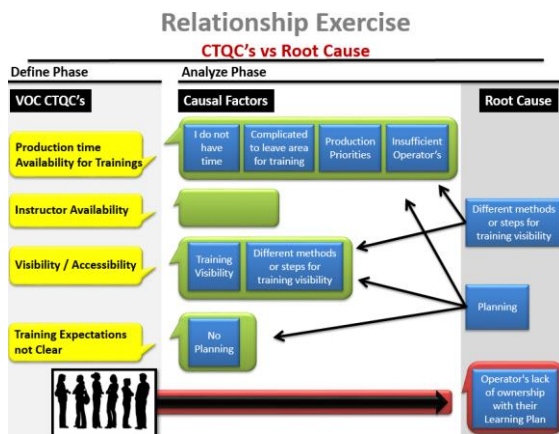
- No planning.
- Operator's lack of ownership with their learning plan.

By working with these 3 root causes we saw that the remaining casual factors could also be targeted. See Figure 17.



**Figure 17**  
Pugh Matrix

Lastly, before moving to the improvement phase a relationship exercise was prepared to compare the identified root causes with CTQC's and previously identified casual factors. The comparison illustrates how the root causes, causal factor and CTQC interconnect. This exercise provides guidance of the right direction before moving to the improve phase. See Figure 18.



**Figure 18**  
CTQC's vs Root Cause Analysis Diagram

Quick win was identified in this phase. The training calendar offering is now showing in the different manufacturing television monitors commonly used for announcement. Providing visibility to operators.

### Improve Results

In the improvement phase the group was gathered to identify what can be done so that training does not go overdue. A total of 22 improvement ideas were identified. The ideas were organized using an affinity diagram with the root causes previously identified in the analyzed phase. The ideas were weighted as of strengths and weakness of each potential solutions. The top criteria's were:

- Have everything I need in only one system.
- Incorporate training sessions in the learning plan.
- Configure training invitation in my calendar as a reminder.
- Supervisor's plan area activity incorporating training.
- Learning plan system orientations.

Criteria's were analyzed and improvement were identified and implemented as follows:

- Learning system management orientations were provided to all operators and shift supervisors. This allows to clarify any doubts and shows them all the convenient tools they have available.
- Training documents were migrated to a location in the document management system as public. Where now operators can access from their learning plan at any time. A total of 107 documents were relocated and waiting time from 6hrs - 65hrs went down to 0 waiting time.
- The training department activated a function where operators can see the training offering from their learning plan. Now they don't only rely from the email announcements sent by the training department. They have everything in one system, see their learning plan, obtain the training document, see offering and when they register an automatic invitation is setup in their calendar that works as a reminder.
- Sessions during the night shift are available.

- SOP will have a minimum of 15 days to put effective to allow enough time for training.
- Instructor led training that in its revision have little or no high impact changes are available as a self-study
- More computers available
- Low impact safety trainings will now be offered by identified operators by management to ease the training process within their shifts.
- Lastly, a pilot plan was set in place for shift supervisors. This pilot plan consists of having a document where they were able to easily plan area activities incorporating trainings. The pilot had a duration of 4 weeks. Once approved by shift supervisors as for meeting their expectation, this document was set setup with macros in excel. For shift supervisors planning training activities for operators took them an average of 49 mins, now it only takes them 5 minutes. For this tool they only have to insert a list of operator's missing, select their shift and press update data. The outcome will be a file with operator's name, training missing, and information of the date, time, location the training will be offered. This tool was a great implementation to help shift supervisors have fast visibility and management. This tool provided to be printed and located in the control room for operators to view.
- It was made clear to management that we had a culture issue as to clearly establish responsibilities. Management met with operators to clarify that they are directly responsible for completing their trainings on time. And shift supervisors will support, facilitate and coordinate area activities so that they can assist to trainings.

### **Control Results**

For improvement sustainability, monthly metrics visibility to supervisors will be sent by the Training Department. Process Owner's will monitor their teams remain under the 15% overdue thru their process team meetings. Action items will

be established and discussed with shift supervisors. The training department will continue to simplify instructor led trainings to convert to self-studies. Management will support and ease the process for operators training time completion.

### **CONCLUSION**

All improvements were implemented. Once the control phase was reached, we measure our project goal and saw that metrics exceeded the goal. Teams 1 and 2 reached a 0% overdue. This project focused in the client and was able to make adjustments that eased the process for operators and shift supervisors. Also made management aware that they are essential in the sustainability of the improvements.

### **REFERENCES**

- [1] B. Henderson and J. Larco, *Lean transformation: How to change your business into a lean enterprise*, Oaklea Press, 2000.
- [2] J. Maxey, M. Price, D. Rowlands and M. George, *The Lean Six Sigma Pocket Tool Book*, New York, USA, McGraw-Hill, 2005.