

# ***Lean Transformation Strategic Journey: From an Ordinary Manufacturing Site towards a World Class Manufacturing Site***

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**Abstract** — *The MDP Company is a global medical device leader company in musculoskeletal healthcare market. One of its primary manufacturing facilities is located in Puerto Rico where orthopedic implants and reconstructive products are manufactured and packaged. The site consists of two manufacturing buildings designed in over twenty manufacturing cells divided by product families and operates three shifts a week with over 500 employees. This project was focused on the identification and implementation of different lean manufacturing tools to reduce in three days the lead time through all manufacturing operations and to improve the manufacturing processes, thus, reduce production costs and convert the Puerto Rico manufacturing facility in one of the most profitable sites for the company. Before project start the average manufacturing lead time was 9 days with a work in process inventory cost of \$2.7 million. By the end of this project, the lead time in pilot manufacturing cell was reduced to 6 days. To achieve project goals, the DMAIC (Define-Measure-Analyze-Improve-Control) Methodology was used and different lean manufacturing tools/concepts were implemented.*

**Key Terms** — *DMAIC, Lead Time Reduction, Lean Manufacturing, Process Optimization.*

## **INTRODUCTION**

The MDP Company is a global medical device leader company in musculoskeletal healthcare market. The company offers a comprehensive and diversified portfolio of musculoskeletal solutions. One of its primary manufacturing facilities is located in Puerto Rico where orthopedic implants and reconstructive products are manufactured and packaged.

Of all medical device sectors, orthopedics is perhaps the most difficult for a large company because each section of anatomy requires its own set of considerations. Additional challenges occur since it is a regulated industry. Based on these facts, the manufacturing facility of the MDP Company located at Puerto Rico is constantly challenging its operations to improve their manufacturing processes, reduce production costs and convert the Puerto Rico manufacturing facility in one of the most profitable sites for the company.

The MDP Puerto Rico manufacturing facility consists of two manufacturing buildings designed in over twenty manufacturing cells divided by product families and operates three shifts a week with over 500 employees.

## **PROJECT STATEMENT**

With the intention of keeping us among the primary manufacturing facilities of the MDP Company, we have been carrying out a series of initiatives and projects during the past three years to minimize operations costs maximizing earnings throughout the development and implementation of different lean manufacturing tools and other quality improvements initiatives. The purpose of all these initiatives is consolidated in one big project which its primary intention is to achieve a World Class Medical Device Manufacturing Site.

## **PROBLEM STATEMENT**

Our manufacturing site has a cellular manufacturing distribution, which means that all of the required processes and tools are distributed within working cells dedicated by family of products. These self-contained cells produce our

products from start to finish and then continue to packaging operations. However, the logistic of the machine's layout forced wasting time on operations by the need of the operators to move from one area to another area in order to complete the assigned manufacturing lots. This was a repeated scenario through all our manufacturing cells.

Because of this, a project was started at the third quarter of 2016 for the optimization of the manufacturing areas layout with the intention of improves lead time. It was then when born the idea of a Lean Transformation Strategic Journey to take out our plant from an ordinary manufacturing site towards a world class manufacturing site.

### **RESEARCH DESCRIPTION**

The main purpose of this project is to study, identify and implement the best lean manufacturing tools that may fit to our operations to support our mid-term goal of increase productivity while reducing manufacturing costs without impacting the quality of our products.

### **RESEARCH OBJECTIVES**

This project aims to achieve and maintain consistent lead time reduction in each of our manufacturing operations, leading to increased productivity and reduced production costs related to Work in Process (WIP) inventory. The lead time reduction sought by manufacturing cell will be at least 3 days less than the current lead time.

### **RESEARCH CONTRIBUTIONS**

The main contribution of this project is to reduce in 3 days the lead time through all manufacturing operations and improve production execution that will result in WIP inventory cost reduction from \$2.7 million to \$1.8 million, increasing our cash flow by \$900,000.

An additional contribution is to transform the MDP Puerto Rico manufacturing facility in one of the most profitable sites for the company. Streamlined operations, improved productivity and

quality products delivery will position us as one of the best five cost-effective sites of the MDP Company and as result of this increases our chances of bringing new products to our manufacturing site.

### **LITERATURE REVIEW**

To identify the best options to carry out our purpose of transformation to a world-class manufacturing site and, with this, achieve to be one of the best 5 MDP sites, we explored different lean tools to determine how each tool can improve our manufacturing operations. In order to set the reader on the project's context, the tools selected for our project are listed below, including a brief description of each concept and a summary of how all these tools can help us obtain our target.

#### **6S (5S + Safety)**

5S is defined as a methodology that results in a workplace that is clean, uncluttered, safe, and well organized to help reduce waste and optimize productivity. It's designed to help build a quality work environment, both physically and mentally. The 5S philosophy applies in any work area suited for visual control and lean production. It is known as 5S because of the five stages that all start with "S" in Japanese: *Seiri* or Sort, *Seiton* or Straighten, *Seiso* or Shine, *Seiketsu* or Standardize, and *Shitsuke* or Sustain [1].

6S (otherwise known as 5S + Safety) is a system that aims to promote and sustain a high level of productivity and safety throughout a workplace. While adhering to the 5S principle, the 6S method adds the concept of Safety; therefore, 6S not only helps organizations promote efficient working environments but also establishes a sustainable culture of safety [2].

In simple terms, the 6S methodology helps a workplace remove items that are no longer needed (sort), organize the items to optimize efficiency and flow (straighten), clean the area in order to more easily identify problems (shine), implement color coding and labels to stay consistent with other areas (standardize), and develop behaviors that keep the

workplace organized over the long term (sustain) and identify hazards and set preventive controls to keep workers safe [2].

### **Bottleneck Analysis**

A bottleneck analysis is a detailed process in which a company gathers as much information about the manufacturing flow of a particular product or process. Specifically, data is gathered about the step(s) in the process where work is bottlenecking [3].

The bottleneck analysis identifies which part of the manufacturing process limits the overall throughput and helps to improve the performance of that part of the process [4]. No matter how fast individual machines or processes will perform, the overall output will only ever flow as fast as the slowest part of the chain [1].

Identifying the root cause of a bottleneck, allow us to implement long-term improvements that will keep the problem from happening again in the future. Once the bottleneck is addressed, a streamline workflow can be maintained and the operations can flow through from start to finish in at an even rate [3].

An additional benefit of the bottleneck analysis is that helps to eliminate waste and improve knowledge. Being aware of the waste is the first step in having it eliminated. Then, the more a company knows about a specific process, the easier it is to make smart decisions. This can provide advantages not only when it comes to eliminating bottlenecks, but when making process improvement decisions in general [3].

### **Continuous Flow**

In the simplest of terms, continuous flow means that parts are moved through operations, from step-to-step, with no work in process in between. It is intended to seek a manufacturing operation where work-in-process smoothly flows through production with minimal (or no) buffers between steps of the manufacturing process [4].

Waiting is perhaps the easiest of manufacturing wastes to overlook. Essentially, this waste occurs

when time is lost as a result of a sag in productivity. The best way to combat waiting waste is implementing continuous flow into production processes [3].

Continuous Flow in the manufacturing operation improves productivity, increases process flexibility, and reduces defects, production lead time, WIP inventory and Finished Goods Inventory to name a few benefits [5].

### **Lead Time Reduction**

Lead Time is the amount of time between process initiation and completion. As part of this project, we will be focused on Production Lead Time which is the amount of time that it takes to build and ship a product if all the materials are available. This includes all the manufacturing, sub-assembly, and assembly processes that impact the ability to process material into a product [6].

Lead time reduction is an important part of process improvement: it leads almost automatically to the question how to remove unnecessary tasks, waste, as well as waiting time from different processes. Looking for lead time reduction opportunities helps companies to focus on improvement actions. A manufacturing company may reduce throughput time by minimizing the time consumed by inspecting, moving and queuing activities [6].

The major benefits of reducing lead times are streamlined operations and improved productivity which results in carrying costs reduction [6].

### **Gemba (The Real Place)**

The term *gemba* comes from Japanese and it means “the real place.” In Lean Management means the actual place where the real work happens [7]. Unless a manager or engineer actually visits the place in which the work is being done and questions the process it will be impossible to fully understand and improve it [1]. Gemba is a philosophy that reminds us to get out of our offices and spend time on the plant floor, the place where real action occurs [4]. Its initial purpose is to allow managers and leaders to observe the actual work

process, engage with employees, gain knowledge about the work process and explore opportunities for continuous improvement [7].

The principal benefit of Gemba is that promotes a deep and thorough understanding of real-world manufacturing issues by first-hand observation and by talking with plant floor employees [4].

### **Kaizen**

*Kaizen* is “change for the better” and is seen as the lean process for continuous improvement of all that we do [1]. It is a strategy where employees work together proactively to achieve regular and incremental improvements in the manufacturing process [4].

Kaizen seeks to eliminate problems associated with the wastes inherent within our processes. The view of any process should be that it is wasteful unless you cannot find a way to eliminate it or do it in a more economical way; everything should be continually challenged and tested [1].

Beyond the obvious benefit of actually improving processes; kaizen engenders team working and ownership when used correctly. Teams have to take responsibility for their areas and are able to make improvements to better their own working experience as well as making things more efficient and saving money for the company. Most people actually want to be successful and proud of the work that they do, kaizen helps them to achieve this to the benefit of the organization [1].

### **Key Performance Indicators (KPI)**

Key Performance Indicators are metrics designed to track and encourage progress towards critical goals of the organization for all aspects of the business. These should be aligned from the top-level company strategy through to what should be achieved within individual cells [6].

The Key Performance Indicators factors are tracked by the organizations to analyze their manufacturing processes. These criteria are used then to measure success relative to a set of predetermined goals or objectives. Therefore, the

best manufacturing KPIs are those aligned with top-level strategic goals, thus, helping to achieve those goals and measure the progress within the organization as well as can be used to raise the bar on to show improvement [4].

### **Total Productive Maintenance**

Total Productive Maintenance (TPM) is a holistic approach to maintenance that focuses on proactive and preventative maintenance to maximize the operational time of equipment. It blurs the distinction between the roles of production and maintenance by placing a strong emphasis on empowering operators to help maintain their equipment [4].

TPM aids to create a shared responsibility for equipment that encourages greater involvement by plant floor workers. In the right environment this can be very effective in improving productivity (increasing up time, reducing cycle times, and eliminating defects) [4].

### **Visual Factory**

Visual Factory is a term to describe how data and information is conveyed in a lean manufacturing environment using a collection of conceptual tools that will convey information in a clear, accurate, efficient, and organized way to those who need to know it. For lean, visual factory consists on the usage of visual indicators, displays and controls used throughout manufacturing plants to improve communication of information [4].

The main goal of the visual factory is to allow everyone to easily visualize all the activities inside the organization thus the current status of all processes is immediately apparent. This information usually includes safety information, process measures and work instructions [8].

### **People**

People are one of the greatest assets no matter what the business is, and are one of the main pillars of lean. Without their creativity and experience it will be hard to succeed and to compete in any business. That is the reason why the companies

must always value and develop their teams to ensure that they get the best from them [1].

Since lean manufacturing focuses on eliminating sources of waste, sometimes when people hear the term “Lean”, they often worry it means eliminating people. In lean, people are what make the system work. Respect for people is an integral part of lean. People understand their own tasks and processes and are in the best place to try to improve them. Rather than seeking to eliminate people, a Lean workplace should seek to eliminate waste. When this means a task is eliminated, the person who performs that task can be reallocated elsewhere rather than let go [1].

### DMAIC Methodology

DMAIC is a structured problem-solving methodology widely used in business. It’s an acronym for the five phases of Six Sigma improvement: Define, Measure, Analyze, Improve and Control. These phases lead a team logically from defining a problem to implementing solutions linked to underlying causes, and establishing best practices to make sure the solutions stay in place as permanent solutions of an existing problem. The DMAIC five steps must be carried out in order, i.e. define, then measure, then analyze, then improve, then control. Each step is typified by various actions as shown in figure 1 [9] [10].

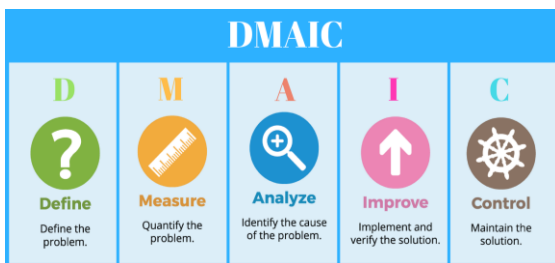


Figure 1  
DMAIC Methodology

## PROJECT METHODOLOGY

Since the purpose of this project is to achieve and maintain a consistent lead time reduction in each of our manufacturing operations which will lead us to increase productivity and reduce production costs, we looked for a simple and

structured methodology that guide us to achieve these goals at the same time that we continue with the manufacturing operations with minimal or none interruption on the day to day business.

That was the reason why the project for our site lean transformation strategic journey was structured based on the DMAIC methodology. The problem statement was studied and analyzed as a whole. Then, different lean manufacturing tools were identified to be implemented based on better fit for current/baseline processes.

Due to the fact that we have the same issue on all manufacturing cells and limited resources assigned to the project, we decided to start with a pilot cell to have minimal impact on the day to day. Once we obtained the expected results on the pilot cell, we continued moving forward with other cells by implementing the same lean tools one cell at a time.

## RESULTS AND DISCUSSION

The results discussed in this section correspond to Pilot Cell improvements implemented using the DMAIC methodology and different lean manufacturing tools as identified based on the problems to be resolved. Details for the tools used and results obtained are shown below.

### Define

The Define Phase was conducted by completing the project charter (figure 2). The project charter captures and summarizes the elements of the project by explaining the problem statement, project objective, business case, assumptions/ constraints, the scope of the project, milestones and team members/resources.

During the Define Phase the Voice of Customer (VOC) tool was used by conducting focus groups meetings to get feedback for existing processes and propose improvement ideas. As result of the Focus Groups and Kaizen events, the first lean tool identified to be implemented was 6S because it can easily eliminate the waste time resulted from a poorly organized work area.

## Measure

During the Measure Phase we evaluated the current state of our processes by comparing what is happening now to what is desirable in the future. For that purpose, we made an analysis of the current state of the manufacturing process for the manufacturing cell selected to be the pilot cell.

To establish a baseline, the first step was to evaluate the manufacturing cell layout. This pilot cell has a total of 34 machines / equipment in a total work space area of 6,811 ft<sup>2</sup> for the manufacturing

of 8 product families. An average manufacturing lead time for these product families is 9 days.

A spaghetti diagram was conducted for each of the manufacturing operations executed in the pilot cell. Figure 3 shows an example of the spaghetti diagram obtained for one of the product families manufactured in pilot cell. The analysis conducted evidenced an operator travel of 2,564 ft per lot. The logistic of the machine's layout forced wasting time on operations by the need of the operators to move from one area to another area in order to complete the assigned manufacturing lots.

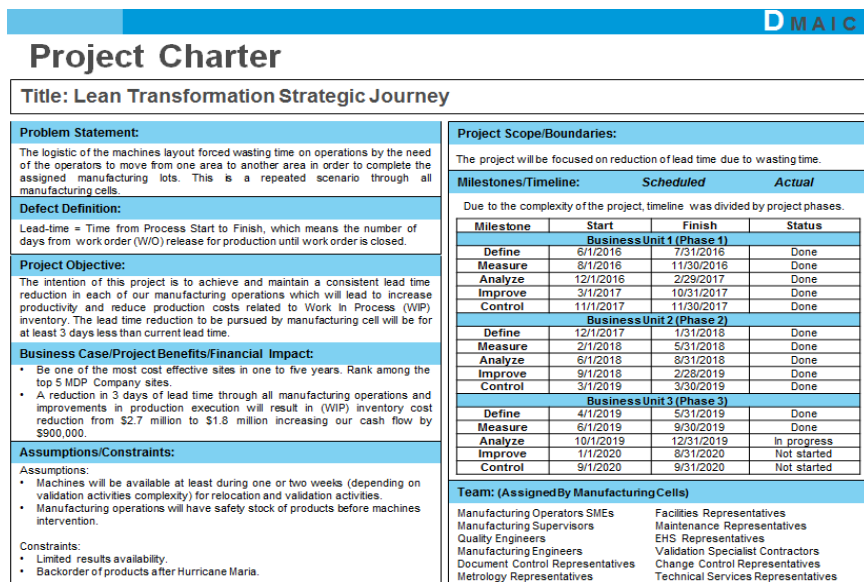


Figure 2  
Project Charter

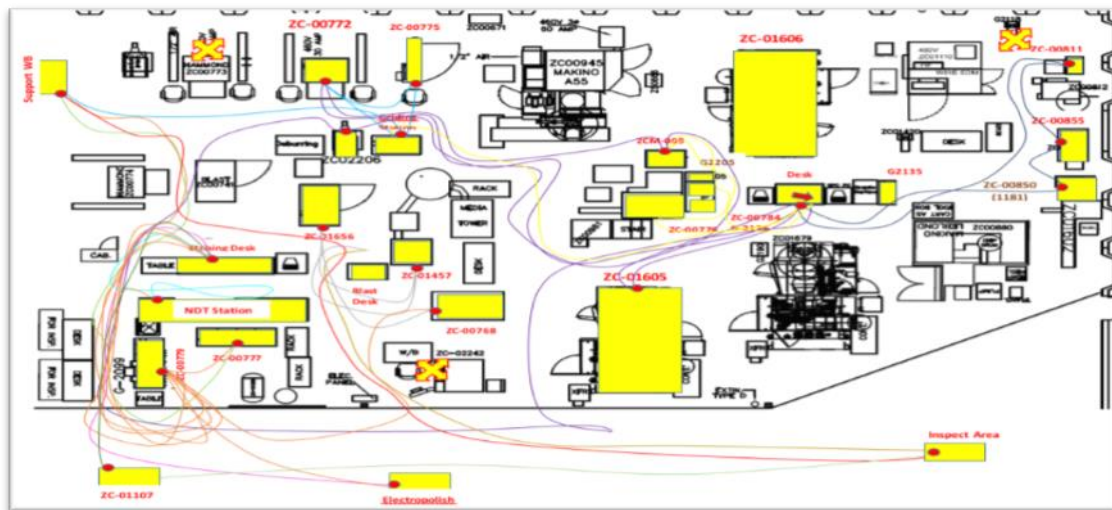


Figure 3  
Spaghetti Diagram

## Analyze

As part of the Analysis Phase, we were pursuing the use of fewer equipment / machines to reduce and maximize the manufacturing workspace. Therefore, we performed a bottleneck analysis to ensure that manufacturing will have continuous flow independent if we have fewer machines. As result of the bottleneck analysis, the manufacturing operations identified to be consolidated in fewer machines were those having less cycle time, thus not impacting any operations.

Table 1 shows the proposed workspace area and quantity of equipment reduction identified for pilot cell as a result of the Analysis Phase.

**Table 1**  
**Proposed Workspace Area and Equipment Reduction**

	Actual	Proposed	Reduced
Area (sq. ft.)	6,811 ft <sup>2</sup>	3,832 ft <sup>2</sup>	2,979 ft <sup>2</sup> (44%)
Quantity of Machines in Pilot Cell	34	26	8 (24%)

## Improve

During the Improve Phase, the possible solutions to the identified problems were developed and implemented. For this phase, we implemented some different lean manufacturing tools to obtain the expected 3 days reduction in lead time. A summary of the lean manufacturing tools/concepts implemented is included below.

- **5S/6S:** This was the first improvement action implemented for our lean transformation strategic journey. By the implementation of this easy and economic lean manufacturing concept; reduction of wasting time in simple things such as looking for tools for machine setup or gages for parts inspection was immediately visible resulting in productivity optimization and also making the workplace safer. Figures 4 and 5 show examples for before and after 5S/6S implementation.
- **Continuous Flow:** This tool was implemented in different ways; the most significant was the manufacturing cell re-design in U Shape to maintain a continuous process flow based on the manufacturing operations order (pilot cell

have 8 product families and each product family have between 15 to 17 operations). Equipment not in use was relocated to an idle area to improve the manufacturing cell layout maximizing the workspace area only for equipment in use.



**Figure 4**  
**Bin Rack System (Before)**



**Figure 5**  
**Bin Cart Flow System (After)**

- **Bottleneck Analysis:** As result of this analysis, two legacy equipment were decommissioned and replaced by new ones with more production capacity. Additional inspection equipment was also relocated into the pilot manufacturing cell since from the spaghetti analysis it was identified that one of the contributors to the wasting time of the operators by walking within operations was the inspection equipment which was located too far away in other manufacturing cell. Also, manufacturing operations identified as bottleneck were subdivided and added to subsequent operation.

- Kaizen:** Through Kaizen meetings, process optimizations were identified for machining operations generally related to the machine setup and compensation / adjustments. These optimizations were validated and then the process capability statistical tool was implemented to maintain process controls on manufacturing operations. Waste elimination due to optimization and process standardization resulted in 80% inspection reduction, thus,

productivity increased for multiple product families.

- TPM:** Total Productive Maintenance, although previously implemented at the site, was improved by the inclusion of visual factory. TPMs were revised to facilitate operators understating and also moved from a simple paper template to a detailed visual standard work sheet (figures 6 and 7).

**OPERATOR TOTAL PRODUCTIVE MAINTENANCE (TPM) SHEET FOR CNC**

MACHINE: Mori Seiki	DEPT:
STARTING DATE:	CELL:
MC Number: 208190	

**OPERATOR MAINTENANCE JOBS**

**DAILY:**

- JOB 1:** Measure the viscosity of the coolant with a calibrated refractometer. Normal reading is 8%. If reading is <6% add coolant, if reading is > 8% add water.  
 (For equipment of Cell 228 the coolant normal reading is 8%, if <6% add coolant, if > 8% add water)  
 To calibrate the refractometer, clean the window and add clean water  
 Adjust the refractometer calibration screw until the reading is "0".
- JOB 2:** Check level(sight glass) of coolant reservoir and add coolant of water if required.  
 Verify Filters and clean if necessary.



Figure 6

Old TPM Template (no clear or specific instructions)

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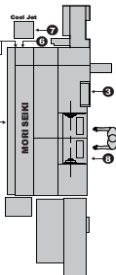
**Total Productive Maintenance Standard Work Sheet (TPMSWS)  
Mori Seiki NZ2000 /Cell 208**

**General Instructions**

**JOB ACTIVITY DESCRIPTION**

Following is a list and a brief description of the job activities required to complete this TPMSWS (refer to drawing below).

JOB 1 - Coolant Viscosity Check	JOB 5 - Hydraulic Unit Pressure Check
JOB 2 - Coolant Level and Filters Cleaning Check	JOB 6 - Air Pressure Regulator Check
JOB 3 - Lubricating Unit Oil Check	JOB 7 - Coolant Oil Level Check
JOB 4 - Hydraulic Unit Oil Level Check	JOB 8 - Safety Interlock Check



**EQUIPMENT AND MATERIALS**  
The following equipment and/or materials are necessary to perform the activities described in this TPMSWS:

• Calibrated Refractometer	• Vactra #2 Oil
• Coolant - Nalco Tech Coolant / P/N: 91-0000-501-00	• Velocite #3 or #6 Oil
• Water	• Mobil DTE 24

Refer to OCP 17.105-ZC, Manufacturing Materials for Femoral Head Cell 208 for additional details.

**Job Task Steps**

Figure 7

New TPM Template (clear and specific instructions)



- **Visual Factory:** Through a combination of signs, charts and other visual representations of information we improved things from TPMs until KPI information dissemination promoting a good communicated environment.

### Control

Our project is constantly monitored at Gemba Boards. We had the culture of Gemba Meetings with top management, planning and supervisors on daily basis. Also, we recently implemented a second tier of Gemba Meetings to incorporate group leaders and operators.

Key Performance Indicators had been also recently implemented at the company. The intended is to develop a high performing culture thru the implementation of QCDP (Quality, Cost, Delivery, People) goals and metrics. The KPIs metrics are centrally exposed at the manufacturing operations to let all know how we are doing our job in our day-to-day business (figure 8). This is another way to monitor the project's benefits and identify any additional required improvement.



**Figure 8**  
**KPI Monitors**

Another mechanism to maintain and sustain the solutions implemented and probably the most important for our lean transformation strategic journey is the people engagement. MDP Company at Puerto Rico is promoting a future state of culture driven towards culture change (Table 2). With that in mind we are working on the creation of skill matrix or gap assessments, cross training plans and also implemented an internal Leadership Academy.

The Academy started with exempt employees and is currently in deployment phase for hourly employees.

**Table 2**  
**Culture Change**

From...	To...
Bureaucracy	Agile
Victim Mentality	Empowerment
Finger Pointing	Accountability
Fear to Raise Your Hand	One Team, One Fight
Poor Decision Making	Continuous Improvement
No Commitment to Results	Drive for Results

### CONCLUSION

The objective for this project is to achieve and maintain a consistent lead time reduction in each of our manufacturing operations which will lead to increase productivity and reduce production costs related to WIP inventory. The lead time reduction to be pursued by manufacturing cell is at least 3 days less than current lead time.

To achieve the lead time reduction goal, a DMAIC methodology was used in a pilot cell. To execute the project, different lean manufacturing tools were used for the implementation of improvements connecting each of these tools to achieve our common goal.

Our lean transformation strategic journey is being implemented in different phases, the one described in this paper was the first step that the MDP Company, Puerto Rico Site, implemented to achieve the transformation from an ordinary manufacturing site towards a world class manufacturing site.

In our journey for re-structuring the manufacturing operations, pilot testing actions and results were as follows:

- Achieve better Operational Performance supported by a Culture-Shaping process and New Lean Design.
- Implement 5S/6S to reduce waste time for simple things such as looking for tools for machine setup or gages for parts inspection resulting in productivity optimization.

- Re-design manufacturing cell in U Shape to maintain a continuous process flow based on the manufacturing operations order.
- Relocate equipment not in use to an idle area to improve the manufacturing cell layout maximizing the workspace area only for equipment in use.
- Split manufacturing operations identified as bottleneck.
- Optimize process for machining operations related to the machine setup and compensation/adjustments and implement process capability statistical tool to maintain process controls on manufacturing operations.
- Optimize and standardize processes resulting in 80% inspection reduction.
- Improve TPMs by the inclusion of visual factory, frequent maintenance avoids risk of unpredictable down-time due to equipment repair.
- Implement a second tier of Gemba Meetings to incorporate group leaders and operators.
- Implement KPIs for QCDP (Quality, Cost, Delivery, People) to achieve a high performing culture.
- Promote a future state of culture driven towards culture change.
- Create skill matrix or gap assessments, cross training plans and implement a Leadership Academy to encourage people development.

In conclusion, by proper deployment and use of the correct problem-solving methodology in combination with proper lean manufacturing tools we will obtain one of the best standing positions within the company improving our performance results that will positively impact the company financials.

Financial benefits that will be obtained from this project once all manufacturing cells completed the DMAIC process will be a WIP inventory reduction from \$2.7 million to \$1.8 million increasing our cash flow by \$900,000.

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