

A Strategically Systematic Approach to Acquire Improvement Project Prospects in a Medical Device Company

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Abstract — *Numerous companies begin their manufacturing improvement journey lacking an overall game plan. This results in a not strategized and structured improvement implementation with results less than optimal and if the results are good, it's because the company is decent at firefighting. The use of Value Stream Mapping as a standard tool to identify and plan improvements will set the roots for a strong improvement project prospects system. Value Stream Mapping can provide a one page representation of all processes that occur from order placement through order receipt by the customer. This snapshot helps an organization, in this case, a medical device company, to identify non value adding activities in a current process and the opportunities for improvement.*

Key Terms — *DMAIC, Information and Material Flow, Lean, Value Stream Mapping.*

INTRODUCTION

The past years have been challenging for medical device companies in Puerto Rico given the tough economic conditions and an uncertain healthcare environment. In order to survive this situation, the medical device company is entitled to focus in cost reduction, creative ways to manage restrictive regulatory environment and incremental profits in sales. In addition, product quality and feasibility should be guaranteed in parallel with financial reductions.

Given these challenges, the medical device industry has been in the need of making strategic plans to efficiently manage their businesses. Currently, several companies focus all their efforts in preparing the next year's budget without knowing what the next year's objectives are. This

situation leads to poor management of resources and projects, putting at risk the business's priorities which are reducing costs, material and overhead to maintain market competitiveness.

This project will be focused in the analysis of a medical devices major product process. Due to the lack of a systematic standard tool to develop project ideas for a continuous improvement journey, this research will follow the DMAIC Methodology along with the value stream mapping tool.

RESEARCH DESCRIPTION

A worldwide manufacturer of medical devices revealed that there is no systematic approach neither a standard tool to develop project ideas for the continuous improvement journey of a medical device company. This affects the site metrics and dramatically risks the 12.5% reduction in VIP, (value improvement projects), dollars of VOP (Value of Production) committed and required yearly by the business.

RESEARCH OBJECTIVES

Design and develop a YOY (year over year), systematic approach to acquire project ideas to fulfill the % VIP of VOP commitment. Design and develop a standard tool accessible to the whole medical device site's population to gather project ideas. Creates the baseline to improve upon and serves as a communication tool. Identify sources of waste and the reasons that they exist to develop opportunities for improvement.

RESEARCH CONTRIBUTIONS

Customer Benefits: The Finance Department will compares the project ideas equivalent to the %

VIP of VOP against the goal; 12.5%. Business Benefits: This systematic approach and standard tool will:

- Allow a common language throughout the organization and will tight together lean concepts and techniques.
- Support the planning, prioritization and implementation plan of the medical device site's VIP and SQP, (Strategic Quality Plan) opportunities.
- Embrace the continuous improvement culture.

LITERATURE REVIEW

Several outstanding leaders in the lean world such as Taiichi Ohno, Womack, Jones, Daniel. T. Jones, Rother, Shook, Peter Hines and Nick Rich have studied the implementation of VSM effectively in the last twenty years. In principle, Value Stream Mapping is a visualization tool oriented to the Toyota version of Lean Manufacturing, (Toyota Production System) [1]. It helps to understand and streamline work processes using the tools and techniques of Lean Manufacturing. Lean is the relentless elimination of waste in every area of operations with the aim of reducing inventory, cycle times and costs so that delivering higher quality patient services can be provided in the most efficient, effective and responsive manner possible, while maintaining the economic viability of the organization. Lean exposes and reduces waste and makes continuous improvement possible [1]. The goal of VSM is to depict material and information flows across and throughout all value-adding processes required to produce and ship the product to the customer. Value Stream Maps document all of the processes used to produce and ship a product, both value-adding and non-value-adding (waste) processes [1]. Waste being any activity that does not add value in a process therefore a potential project opportunity. VSM can thus serve as a project originator tool to help management, engineers, production associates, schedulers, suppliers, and customers to save costs by completing those projects. As a result, VSM is

primarily a communication tool, but is also used as a strategic planning tool, and a change management tool. Toyota have been benefiting since 1940's, from Material and Information Flow Mapping. Taiichi Ohno (1988) could not see waste at a glance (especially across a geographical area). He developed Material and Information Flow Mapping (VSM) as a standard method for mapping the flows visually and it became the standard basis for designing improvements at Toyota - as a common language [2]. It became one of their business planning tools. VSM is now utilized throughout the world, in many businesses to strategically plan and it is the starting point to any lean transformation and implementation.

Womack and Jones (1998) and Moore (2006) have stated that, the organizations of many types are implementing lean manufacturing, or lean production, practices to respond to competitive challenges [2]. They have mentioned that lean initiatives can be taken up in the fields of automotive sector, aerospace, and consumer goods industries around the world. Moore has discussed various implementation tools of Lean Manufacturing, which can be incorporated in the industries [2].

Rother and Shook (1999) have discussed that VSM is used to define and analyze the current state for a product value stream and design a future state focused on reducing waste, improving lead-time, and improving workflow. The use of VSM appears to be increasing, particularly since the publication of "learning to see" by Rother and Shook (1999) [2]. One of the unique characteristics of VSM in comparison with other process analysis techniques is that one map depicts both material and information flow that controls the material flow [3]. The focus of VSM is on a product "value stream" (all actions required to transform raw materials into a finished product) for a given "product family", products that follow the same overall production steps.

Doolen et al (2002) have extended the applications of lean production techniques in the electronics manufacturing perspectives. Hyer

(2002) has implemented Lean manufacturing in the office service and administrative processes. Badrinarayana and Sharma (2007) discusses that the interdependent components form the value stream and Value Stream is the set of all specific actions required to bring out a specific product. In order to attain noteworthy improvements the Zayko, et.al (1997) have decided to use VSM to visualize the entire flow and select lean tools that yielded maximum benefits [4].

Hines and Rich (1997) has quoted that, the value stream is “the specific activities within a supply chain required to design order and provide a specific product or value”.

Simchi-Levi et al (2004) are of the opinion that the customers are always concerned with their order status, and sometimes they value the order status more than a reduced lead time [4]. But, McDonald et.al (2002) point out that the VSM creates a common language for production process thus is facilitating more thoughtful decisions to improve the value stream. This will effectively reduce the wastes and improves the productivity. While researchers and practitioners have developed a number of tools to investigate individual firms and supply chains, most of these tools fall short in linking and visualizing the nature of the material and information flow in an individual company. McDonald et.al (2002) have used simulation techniques for the high-performance motion control products manufacturing system to demonstrate that, simulation can be a very crucial tool in assessing different future state maps. They demonstrate that simulation can provide and examine different scenarios to complement those obtained from future state mapping.

The VSM was extended in the field of aircraft manufacturing also. Abbett and Payne (1999) have discussed the application of the tool in an aircraft manufacturing unit. They have developed the current and future state maps with the objective of reducing lead-time according to customer's requirements.

New (1993), and Jones et.al (1997) and other researchers developed individual tools to

understand the value stream. VSM extends guidance for improvements in the process, identifies the need to improve workflow and finally shows avenues to reduce waste.

Shingo (1989) has discussed the strategies for the effective implementation of VSM in a wood industry. He also opines that loops can be formed to identify the similar processes and these loops will be helpful in identifying the non-value activities in a systematic manner. He has suggested the ways to eliminate non value added activity and proposed measures to increase the Value added ratio.

Yang-Hua and Valandeghem (2002) describe, VSM as a mapping tool that is used to describe supply chain networks. It maps not only material flows but also information flows that signal and control the material flows. The material flow path of the product is traced back from the final operation in its routing to the storage location for raw material. This visual representation facilitates the process of lean implementation by helping to identify the value-added steps in a value stream, and eliminating the non-value added steps / waste (muda) [4].

Every time a VSM is completed the team responsible for the creation often, examined the snapshot and questions these types of processes as followed: what is the value-added ratio of these supporting processes to the organization? Do the current plans of manufacturing should remain internal or has to be outsourced? How much WIP (work in progress) is accumulated? How long the process does really takes? All these discussions have prompted the authors to carry out VSM as a useful tool to explore additional redesign opportunities, set targets and to propose for the future performance levels [4].

This encouraged the authors to study thoroughly the processes of manufacturing and have drawn Current VSM for all the processes and carried out brainstorming sessions with the managers and engineers concerned to arrive at Future VSM and have suggested action plans to be taken to effectively implement a Future VSM.

METHODOLOGY

A model plan was developed to fulfill a temporary endeavor undertaken to create a unique result through progressive elaboration in all its nature. After a detailed discussion with sponsors and stakeholders it is been determined to select the highest volume product as pilot run for this project. To complete the project a step-by-step methodology approach is been selected, see Figure 1, that encompasses a roadmap and tools to identify and eliminate waste in the office and transactional environment [5]. This approach will be documented as followed:



Figure 1
DMAIC Methodology

Define Phase

Recognizing that a project should begin and committing to do so. The purpose of the Definition Phase is to refine the business opportunity, define the technical and product performance requirements, and establish a work plan for the balance of the project. The Core Team is established at the start of this phase. Critical project elements must be understood in sufficient detail for the Core Team to determine project risk, resource requirements, and commit to a final schedule [6].

Key accomplishments include:

- **Business Case:** Why this project?
- **Problem Definition & Problem Statement:** Is a brief description of the problem. A correctly defined problem is a problem that is 50% solved [6].
- **Goals/Objectives/Measures of Success:** a tangible, measurable and verifiable result.

- **Expected Benefits (including estimated cost savings):** Summarize the customer benefits of project completion.
- **Project Timeline:** Establishing a timeline, with realistic and attainable deadlines, will make sure that you spend appropriate amounts of time on each step of the process and help keep you on track.
- **Voice of the Customer (VOC):** A process used to capture the requirements/feedback from the customer (internal or external) to provide them with best-in-class service/product quality. If voice of the customer requirements are done well, planning becomes easier; if planning is done well, execution becomes easier [7].
- **Project Charter:** It is a life document in where all the agreements are documented and signed. It is to develop goals, scope, roles/responsibilities, physical deliverables and metrics of the project; it helps you define scope and provides you with one clear problem statement on which to focus [7].
- **Management Engagement:** Management commitment. It provides direct oversight of Project Management within an organization. Project communications management, includes processes required to ensure timely and appropriate generation, collection, dissemination, storage and ultimate disposition of project information [8].
- **Kickoff Meeting:** is the first meeting with the project team and the client of the project. This meeting would follow definition of the base elements for the project and other project planning activities. This meeting introduces the members of the project team and the client and provides the opportunity to discuss the role of each team member. Also is where the sponsor encourages the team and support them towards the goal.
- **Summary & Conclusion:** This is the “gate review” - the glue that holds the DMAIC methodology together. There is a review to ensure the objectives for the phase have been

met before proceeding to the next phase. This does not need to be a formal meeting; just a quick check to make sure everyone is on the same page before going too far down the project path [8].

Measure Phase

Map and measure the process to understand the current state. Determine an appropriate way to measure the process performance and collect the data, develop a data collection plan for the process and collect the data.

Key accomplishments include:

- Develop current state map. A current state value stream is a snapshot of a value stream as it exists at the time of observation.
- Visualize potential issues with process flow
- Specify and evaluate process metrics

Analyze Phase

Analyze current state to identify ideas to eliminate waste & streamline the process. Determine root causes of defects and opportunities for improvement. Identify gaps between current performance and goal performance and prioritize opportunities to improve.

Key accomplishments include:

- Investigate rationale for current state
- Analyze 7 forms of waste
- Identify Non-Value Added Activity

Improve Phase

Develop future state and implement ideas that will improve the process. Design and test creative solutions to fix and prevent problems.

Key accomplishments include:

- Ranking of Improvement Ideas
- Prioritize Improvement Activities
- Develop Improvement Plan

Control Phase

Monitor and verify process improvements to sustain results. Make sure the improvement is sustainable and create monitoring plan to verify that

a process stays within defined limits. Deploy solutions and institutionalize the improvements.

Key accomplishments include:

- The Finance Department will compares the project ideas equivalent to the % VIP of VOP against the goal; 12.5% in a monthly basis.
- A new metric will be monitor in a quarterly basis called number of ideas per employee implemented vs. number of ideas per employee suggested.

RESULTS AND DISCUSSION

This section discusses all the implementation activities for the Strategically Systematic Approach to Acquire Improvement Project Prospects using the DMAIC Methodology.

Define Phase

In the define phase a project charter, refer to Figure 2, was developed as a life document in where all the agreements were documented and signed by the management team. The document provides the project title, project leader, technical mentor, project sponsor, start date, target completion date, problem statement, process, project goal, benefits, project scope, team members, deliverables and activities with responsible and dates.

Project Title	Site Value Stream Map
Technical Mentor	Leila Rosario
Project Sponsor	Olga Gonzalez
Start Date	09 Apr 2012
Target Date	31 Dec 2012
Problem Statement	On 2011 there was no VIP project identified for 2012. At the DOR site there is no formal tool to develop project planning and prioritization.
Project Goal	A systematic and qualitative tool to describe in detail how the facility should operate in order to create flow. Tool that uses a common language and

	will tight together lean concepts and techniques. The tool will support the planning, prioritization and implementation plan of DOR VIP and SQP opportunities and will also embrace the continues improvement culture
Project Scope	IS-4 door to door process/information flow
Benefits	Tool that will help visualize more than just the single - process level. Provides the linkage between information flow and material flow. VSM is good for describing what the site is going to do to affect/impact site numbers.
Team Members	Leila Rosario, Yanira Villarrubia and Luis Rodriguez

**Figure 2
Project Charter**

After the project charter was approved by upper management a kick-off meeting was conducted in where all the management staff participated and supported the selected teams to complete the project.

By the time each and every one of the phases achieved its completion, a formal presentation to upper management is performed as shown in Figure 3.

<u>Project Details</u>	<u>Methodology</u>
Objective: Benefits: Measure of success:	
<u>Project Timeline</u>	<u>Risk/Mitigation</u>
Milestone: Due Date: Status:	

**Figure 3
Upper Management Communication Tool (4 Panel)**

Measure Phase

In the Measure Phase, a value stream selected to be mapped is a high volume product and the goal is to create a snapshot of all processes that occur from order placement through order receipt by the customer. In order for us to do this a strategy was developed. First of all, a group of subject matter experts were consulted in a special event in where the team creates a high level process map of the value stream selected. With this information the team divided the high level processes in seven pieces that eventually turned to be seven events. For each event a team was selected and these are the set of rules established for these events:

- Time for the event: 8 hours
- Main Goals for the event: Map the current state, identify non value added activities and suggest improvement ideas.
- No action items after the event

To complete the value stream mapping in any of the seven events the team used the 8 Value Stream Steps:

1. Identify Major Product Line
2. Identify Team & Organize For Success
3. Learn VSM Skills
4. Map the Current State: Always Begin at the Customer and Work Upstream. Walk The Flow. NEVER Assume Anything! Map It The Way You SEE It. Collect Data As You Walk Along The Flow...Be HONEST! Don't Get Caught Up In The Details... Keep It Simple. Keep It Simple. Keep It Simple.
5. Identify Opportunities to Eliminate Waste.
6. Map the Future State (Metrics).
7. Develop Implementation Plan (Projects & Timeline).
8. Implement Future State

A set of specific icons, see Figure 4, were identified to be used among the events to picture the material & information flow.

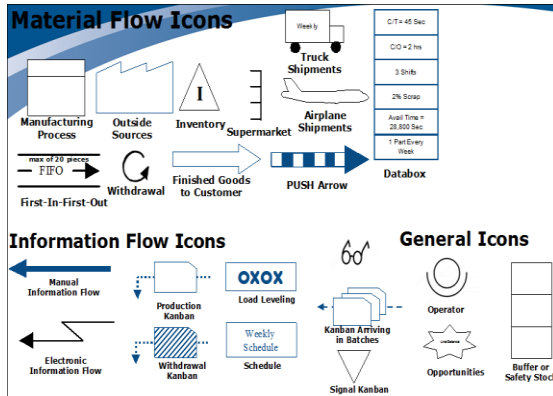


Figure 4
Material & Information Flow Icons

Analyze Phase

During the Analyze Phase we conclude after seven weeks, 278 new project ideas, lots of discoveries, a reality check such as a lead time of 68 days instead of 6 days, 82% non-value added activity vs. 18% value added activity and an enthusiastic team, what the team should do? The project core team developed a model shown in Figure 5 to manage this main event in the future.



Figure 5
Value Stream Mapping Model

The value stream mapping model is intended to be completed in an annual basis to fulfill the company's project pipeline before the budget is prepared, this way the upper management will be able to allocate resources and plan capital money ahead of time. This specific medical device

company already has several systems to run projects from start to finish with the appropriate monitoring tool and also, a good recognition system that allow a cycle such as the value stream mapping model to be successful because it's considering current systems, the culture is embedded.

Improve Phase

For the Improve phase a project prioritization matrix was designed. All the project managers and project tool owners from the site were brought together to developed two areas and ten categories aligned with the business next year's vision to prioritize the 278 new project ideas.

The two categories are Effort and Impact; for Effort, see Figure 6; The categories are: Risk, Resources, Expenses, Complexity and Timing to complete the project; and for Impact, refer to Figure 7; The categories are: Work Content in hours, Quality in % of Scrap, Savings, Amount of Metrics impacted and Timing for benefit. The weighting percentage for each category will vary depending on business needs.

Effort - X Axis	
Category	What is?
Risk	A risk is something that may happen and if it does, will have a positive or negative impact on the project. (Compliance and Patient Safety)
Resources	Resources are required to carry out the project tasks. They can be people, equipment, facilities, funding, or anything else capable of definition (usually other than labour) required for the completion of a project activity
Expenses	Money invested in a business venture with an expectation of income, and recovered through earnings generated by the business over several years. It is generally understood to be used for capital expenditure rather than for day-to-day operations (working capital) or other expenses.
Complexity	Projects can be categorized into complexity classes (e.g., Class I = High, Class II - Med, or Class III - Low). Two factors, project size and project complexity, are used to determine the Project Complexity Class. The Project Complexity Class can then be used as a basis for defining the required levels of monitoring, control, and corporate executive involvement.
Timing	How long does it takes to complete the project?

Figure 6
Category: Effort

Impact - Y Axis	
Category	What is?
Work Content	How long does it take to complete the process addressed in the project selected
Quality [% Rework]	The characteristics of a product or service that bear on its ability to satisfy stated or implied needs. A product or service free of deficiencies. According to Joseph Juran, quality means "fitness for use," according to Philip Crosby, it means "conformance to requirements."
VIP	Savings \$\$
Metrics (9 Panel)	Impact on DOR Metrics (Metrics: Quality - CPM, Qis & Field Actions), Service Level - (Fill Rate & Backorders), Overhead and P&L, Labor Efficiency, Scrap % of VOP, Material VIP, Cycle Time, Inventory DOH and VIP Total
Timing for benefit	How long does it take for the client to receive the benefits of the project? ROI

Figure 7
Category: Impact

The results obtained by the project prioritization matrix provide the medical device company a gamma of projects to be completed the next year and also a baseline for the high volume product mapped. The matrix is easy to understand and managed; it helps any project manager to rank project ideas in the following groups; Low Effort-Low Impact Projects, Low Effort-High Impact Projects, High Effort-High Impact Projects and High Effort-Low Impact Projects, see Figure 8. Obviously, the projects recommended to be completed as a priority are the ones located in the Low Effort-High Impact Group.

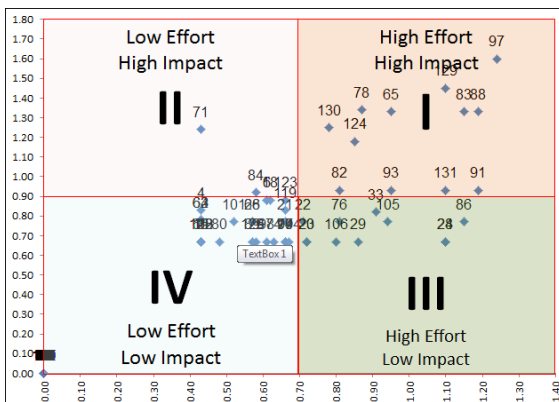


Figure 8
Effort vs. Impact Graph

Control Phase

In the control phase, the Finance Department will compare the project ideas equivalent to the % VIP of VOP against the goal; 12.5% in a monthly basis. In (Figure 9) the VIP Savings were tracked to expose the status of all projects active and inactive

selected by the project prioritization team to fulfill the % VIP of VOP in a monthly basis.

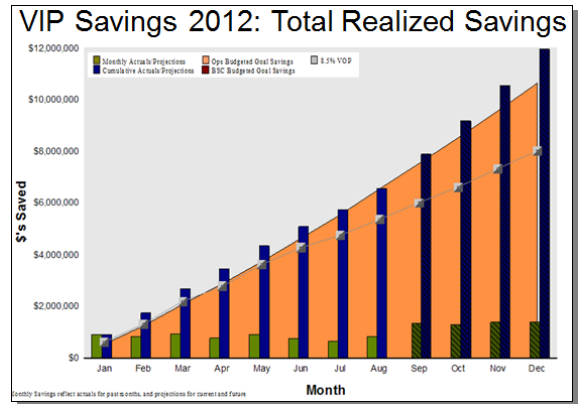


Figure 9
VIP Savings vs. VOP

A new metric will be monitor in a quarterly basis, called number of ideas per employee implemented vs. number of ideas per employee suggested, see Figure 10. System for encouraging voluntary employee suggestions and improvement activities; Formal system that clearly outlines the boundaries within which employees can act on their own, encouraging and acknowledging employees for taking initiative within those boundaries; Company procedures that facilitate all employees sharing problems and exchanging ideas with customer and/or supplier employees; Recruitment and succession planning system that proactively ensures a competitive workforce; etc.

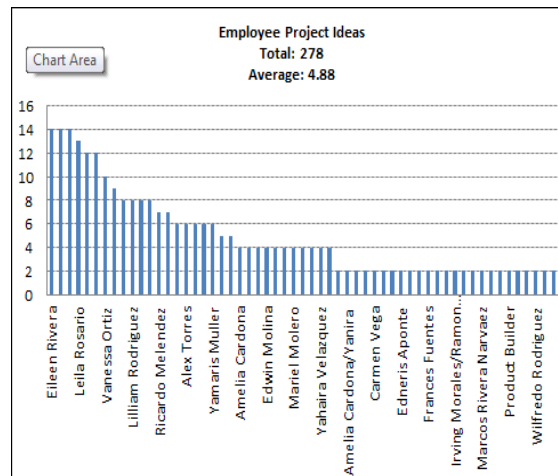


Figure 10
Employee Project Ideas

CONCLUSION

This research validates that the value stream mapping is one of the strongest tools in the current industry environment. The Value Stream Map is a valuable planning tool and can be used for developing and implementing lean improvement projects. The process of creating a Value Stream Map helps to train the team on lean techniques and to reveal opportunities to reduce waste. A completed Value Stream Map can be used as a visual communications tool to explain how lean techniques can reduce waste in the value stream. Value Stream Maps become the first step towards shortened lead times, fast identification of waste in the value stream and the identification of process improvement projects to eliminate the waste and achieve continuous flow.

Finally, the most important thing with this viewpoint is the involvement of all employees of an organization to achieve that ideal project plan that will fulfill the business needs year after year allowing a better allocation of resources, an improved management of projects and a good baseline for any employee interested in his/her process development within the company. Based on these results, the value stream mapping can greatly contribute in this changing global industry for medical devices.

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