CHAPTER OF THESIS SAMPLE

The Implementation of Lean Management Principles for Process Improvement in a Medical Device Company by Using DMAIC Approach

THESIS WRITING SERVICE

Introduction

DMAIC processes are very useful in helping businesses make the right business decisions. DMAIC provides a structured approach for solving organization problems and improving the results of an organization. The flexibility of DMAIC processes makes them very useful in all industries or any form of process improvements (Thomas, 2003). With time the application of DMAIC principles is assumed to transform an entire organization culture to enable the employees of an organization to be continuously looking for chances of reducing waste and adding value to the company processes. This paper seeks to understand how DMAIC processes can be applied in a Medical Devices company to enhance the company processes. To achieve this, a distinct methodology of applying DMAIC principles in a medical device company is developed using several DMAIC methodologies. The research will provide a detailed systematic roadmap for integrating Lean Six-Sigma and eliminate inefficiencies in the company's hydraulic coating processes. Specifically, the aim of this work is developing a unique DMAIC approach for improving the lead-time for company's products, reducing material and time wastage in the organisation.

Company Profile

The company under review has the reputation of being a global leader in the manufacture of medical technology brands. The company was established in 1979 in Ireland to serve many industries as a provider of outsourced engineering services. It ventured into the medical devices industry in the year 2003. The company has specialized in the medical devices industry since the year 2003and has made significant growth in business and market through delivering a combination of new products, acquisitions, geographic expansions, and service and technology developments. In 2010, the company acquired TactXmedical a company that specializes in designing catheters and delivery systems. In the year 2012, the company acquired ABT medical and adopted its balloon design. This deal helped the company to grow its manufacturing capacity using Proprietary SmartformTMtechnology. The company expanded to China in 2013 to gain market share and partnerships in the Asian Market (Creganna, 2016).

The company continued its expansion and growth in the year 2014with the acquisition of Precision Wire Components. This acquisition helped the company to become the leading provider of Minimally Invasive Delivery and Access Devices in the world. This acquisition also helped the company gain a footprint in Oregon and Costa Rica Markets. The tremendous growth of the company has made it have operations spanning the four continents. This company is a major leading provider of Minimally Invasive Medical Devices and outsourcing solutions globally. The company has its headquarters in Ireland and has regional offices in California, Oregon, Costa Rica, Minnesota, Singapore, and China. The company operates as aprivate company (Creganna, 2016).

The Key Drivers of the Company

According to Creganna (2016), the main driver in business is providing a diverse and holistic range of medical products and services to its customers in an innovative way. The company specializes in developing a full spectrum of medical devices ranging from cardiovascular, neurovascular, electrophysiology and oncological. It has medical devices for other specialties such as Laparoscopy, Urology, and Pulmonary, MI orthopaedic, Peripheral, Vascular and Structural heart. The mission of the company is quality, reliability, services and innovation. It offers a comprehensive scope of outsourced solutions to many medical devices companies such as regulatory and clinical support, creative designs,

and excellent manufacturing services. The company is the leading designer of catheters and manufacturing partner for many world-leading brands. The company is the world-leading provider of a wide range of MI catheters like PTCA, EP, Specialty and Niche catheter Thrombetomy and GI Catheters (Creganna, 2016).

The delivery of value to its customers is achieved through its proven and supported solutions for every stage of the product lifecycle. The company specializes in Minimally Invasive Delivery equipment, access devices, and designs and delivers the product to the market. The company offers a range of products, services, and technologies to enable its products reach the market faster and have a market advantage over its rivals. It also facilitates its' customers to identify their core competencies so that the company can focus on them and offers an extensive menu of solutions to customers. It also offers reliable manufacturing, sub-manufacturing, and sub-assembly services to other companies. The company also provides supply chain channels for other company's products and provides continuous improvement processes for other companies' products to drive efficiencies. It also provides optimization services and designing of a new generation of product to its partners. The company offers effective solutions through the complete maturity of medical device products lifecycle during development and growth maturity of a product (Creganna, 2016).

Problems

Despite the company being a global leader in the manufacture and marketing of medical equipment, there are some challenges in some of the company's production processes. The major area of focus of the lean process is the process of hydraulic coating of its products. Hydraulic coating is the process of applying hard face coatings to prevent wear and corrosion on the surfaces of equipment. Some operational bottlenecks in this process slow the process and make it time- consuming as explained below.

Time Wastage

The process of cleaning items meant for hydraulic coating is very time- consuming. The working area layout is inefficient and wastes time. The workers move around due to the inefficient layout of the area leading to wastage of time. The sharing of air supply with other machines leads to the development of low pressure, which leads to machine downtimes, and failure of the machines, which wastes time. The workers have to wait for twenty minutes for the initial coating process to be completed. There are two shifts per week with three workers sharing the shifts.

Inefficient Layout

The packaging area for the equipment's product is near the coating area. There is a high the risk of foreign materials sticking to the coated surfaces of the machines risking damage and development of defects. The packaging area for the hydraulic coating processes is far from the coating area. The packing area is in another building, which leads to time wastage transferring the items to another room and wastage of packaging the materials. The materials are covered with plastic bags before they are transferred to the other rooms, and then the plastic bags are disposed of.

Selection of the Best Tool for Addressing the Company Efficiencies

The operational bottlenecks in the company's hydraulic coating process require the ideal tool for identifying their root causes and solving them. Among the problem-solving tools considered are

DRIVE

According to Taylor (2008), DRIVE is an acronym that stands for Define, Review, Identify, Verify, and Execute. These are the steps followed in this process of problem-solving. Define means identifying the scope or the criteria to evaluate the problem. The review step entails evaluating the existing deliverables, processes, and collection of data about a problem. Identify is identifying the process improvements and the necessary changes required for sustaining all the proposed improvements. Verify is evaluating whether the improvements proposed will attain the defined goals. Execute is implementing all the changes in the plan (Arthur, 2011).This tool is a simple and straightforward method of solving business process problems. However, DRIVE is a simple method of solving business problems not ideal for solving complex -intertwined process issues (Fiore, 2004). It is highly unlikely that complex issues like these facing the medical devices company can be solved using simple problem-solving skills like DRIVE.

Simulation

Basem & Raid (2006) explain that simulation is a computer-based model that imitates the operation of a real system. Simulation models are time-based and factor all the resources and constraints in a project. This process is expensive because of the high functionality required in using time computer-based techniques. The requirements for validation of simulation require the use of data from multiple sources to attain a good level of confidence of its representation in real world dynamics. Simulation is a difficult, time-consuming and costly processes hence not ideal for this study.

Statistical Process Controls (SPC)

According to Hartung (2010) Statistical, process control is an approach to reduce variability in processes, which is the main cause of problems. The decisions made in SPC are based on the analysis of statistical data collected using charts or other methods. It is mostly widely used in quality control in manufacturing. The most common method of using SPC is the control chart that is used to monitor the processes using ranges and means.SPC emphasizes early detection and prevention, but it has the disadvantage of taking so much time in its application. SPC process requires many observations, and the cooperation and training of staff involved in the process, which is costly and time- consuming. There are also problems in the quality of measurements since it reveals when quality has changed but does not define by what percentage the rejected products are defective. The process is also costly since it may also require the services of a consultant and training of staff (Eckes, 2003). SPC is therefore not ideal for this study.

DMAIC

DMAIC is the method of process improvement that was selected for this study. Thomas (2003) Explains that In DMAIC, organization processes are established, variation is evaluated and minimized, and the processes within an organization optimized and improved. The use of DMAIC results in the reduction of errors improved performances and increased productivity and efficiency. DMAIC steps are simple easy to understand and follow a logical sequence. DMAIC steps allow an organization to determine the scope of a problem, evaluate current performance of an organization. DMAIC also helps organizations analyse the causes of problems, and inefficiencies in an organization. DMAIC also helps organizations in testing and verifying the recommendations for improvement and effect any changes. DMAIC steps are easy to use and comprehend. These steps can be applied to any processes or any

industry as a guide to organization improvement (Schonberger, 2008).
Summers (2011) explain the steps of DMAIC are Define-Measure-Analyse- Improve- control.The Define step in DMAIC model is the step that establishes what needs to be there at the commencement of the process. The Define step identifies the objective and the deliverables of the process improvement project. The Measuring step is the step of identifying and defining the key metrics of an organization. Measurement step entails collection of data about the processes of an organization. The measuring step entails building a comprehensive map of the process. The Analysis step entails finding out the cause of a problem through analysing the existing data through a series of tools to determine whether there is any cause- effect relationship with a problem. It is about discovering the causes of the problem. The Improve step entails utilizing the findings of the Define-Analyse-Measure steps to innovate, find, and experiment a solution to a problem. Improve step entails creating solutions and testing their viability through experiments and pilot studies. Schuttta, (2006), explains that the objective of the Control step in DMAIC is to ensure the successful implementation of the recommendations of a team so that long team success is achieved. The Control step also ensures that the new improved processes become the standard operation procedures in an organization. The Control step also analyses the results to prevent a company from reversing back to earlier procedures.
According to Christine, (2007), DMAIC processes are very useful in helping businesses make the right business decisions. DMAIC provides a structured approach for solving organization problems and improving the results of an organization. The flexibility of DMAIC processes makes them very useful in all industries or any form of process improvements. DMAIC focuses on enhancing quality and rationalizing the defects in business processes. Between the process improvement techniques available in Six-Sigma, DMAIC is the most used and effective technique, which ensures that the production process is maintained. DMAIC is well structured since it examines the process carefully before experimenting solutions. This structured method gives businesses a road map to get solutions to their problems and handle issues from the beginning of a project to the end while producing good results for the business. DMAIC also helps businesses to solve complex issues and quantify the improvements made to business (Michael, 2002).The problems in the hydraulic coating process of the company require process improvements since they are easy to measure the process changes using DMAIC methodologies. The issues addressed are complex and intertwined and require a through method of analysis like DMAIC.

Pareto Analysis

According to Furterer (2009), a Pareto analysis is an observation of all the causes of organization problems that are then displayed on a chart or diagram that classifies the causes of problems from the simplest one to the most complex. This method is based on the Pareto principle that states that twenty percent of the effort yields eighty percent of the results. This method is good for improved decision making enhanced problem-solving skills and improving organization efficiency. However, this method has the disadvantage of assigning inaccurate scores to the problem due to failure to assign the proper score for every factor in the Pareto chart. Pareto analysis also disregards the slightest problems that have the greatest impact on businesses (Taghizadegan, 2010).The other major reason why this method is not ideal for this study is the inability of accessing huge amounts of data from the company.

Just in Time Methodology

Just in Time is an inventory strategy that entails ordering materials as per their demand for production.

The aim of this strategy is saving money on costly overheads. This process requires accurate sales forecasts (Michael & John, 2004). JIT method is not ideal for this study because the company utilizes the forecasting method and the nature of the company problems requires a thorough problem-solving tool.

SIPOC Diagram

According to Schutta (2006), SIPOC is an acronym for, Suppliers, Inputs, Process, Outputs, Customers diagram that explains the scope of work for teams in an organization and identifies the deficiencies in quality and scope of process improvement activities. This process identifies feedback from all stakeholders in an organization and jump-starts a team to begin thinking of the cause and effect of problems. SIPOC has the limitation of being a high-level view of problems and requires other processes like detailed process mapping to execute. It is therefore not ideal for solving complex problems
d) Define of experiments also known as experimental research is a compilation of research designs, which utilize controlled testing and manipulation to understand processes. It is useful where there is a time priority and consistency in relationships. Define of experiments also ideal for use if the correlation is huge, hence not ideal for solving complex problems (Summers, 2011). It is difficult to carry these experiments in a manufacturing setting.

Failure Mode Defects and Analysis (FMEA)

According to Arthur (2011) Failure Mode Defects and Analysis is a method used in determining the most probable areas of failure of designs, processes, and their causes. FMEA is used in designing a process, reviewing it, and improving it. FMEA acts as a method of controlling efficiency. This technique is a systematic technique that identifies failures through analysis and then estimates the effects of failure through devising good ways of controlling failure so that flaws can be averted. If FMEA process is done in the right way, it is effective in evaluating designs processes and areas that need improvement and act as a guide for the development of new processes. The method is a logical way of identifying the areas of focus while at the same time reducing cost and time of development. The major pitfall of this method is it lists failure modes depending on risk, and this does not eliminate the failures unless augmented by other processes. It has a bias towards risk ratings.

Statistical Process Controls

SPCs are techniques for measuring and evaluating quality in manufacturing processes. Data is obtained in the form of process or product measurements in real time. This data is then displayed in a graph with some predetermined control limits determined by the process capabilities. If data falls within the control limits, then everything is operating normally. If there is, any variation in data from the control limits, then an assignable cause is detected (Furterer, 2009). This process requires the use of control chat and data. This data was not accessible from the company hence SPC was used.

(TQM) Total quality Management

Fiore (2004) explains total quality management as a management approach that focuses on long-term success through satisfying customers. Under this approach, all the members of an organization focus on improving processes products and culture within an organization. This method uses data strategies and effective communications to integrate quality and discipline into the culture of an organization. In some instances, some core values and principles on which an organization operates are defined.

This method was not ideal for the study because the management of the company could not participate in the process. The implementation Of Total Quality Management entails the implementation of many methodologies and techniques that do not define a prescriptive method of its implementation in organizations

The best tool for use in this study was DMAIC.

Define Step of DMAIC

In the step, a flow chart was used to analyses the processes in the hydraulic coating process and identify problems with the process. The flowchart lists the company steps in sequential order and all the materials and people involved in the process to map out areas of inefficiency and operational bottlenecks. From this flowchart, the following was observed

1) The waiting period before moving from one-step to the other is long and time wasting. This period is brought about by the inefficient layout of the work processes and long periods taken preparing items for the next steps. The waiting period before the first coating process begins is twenty minutes.

2) The Hydraulic coating process has too many processes and movement of items between the different areas of the room resulting in unnecessary movements.

3) Over-processing of items caused by double packaging procedures

2) The Measurement step

In the measurement step, value stream mapping was used. Value stream mapping is a flow chart that uses specialized symbols in depicting the flow of information and inventory in an organization. The purpose of a value process map is providing optimum value to all the customers through the complete value chain of an organization with less waste in design technology and sustenance through the product lifecycle and service. Value process map enables a business to see waste and evaluate them value streaming entails the use of seven steps (Taylor, 2008).The first stage is the choice of the product or several products that are to be mapped or the process, which in this case was the hydraulic coating process. The next step was the selection of symbols to be used for the processes and defining the boundaries of the process, the collection of data and production of current state maps of the process times, information flows, demand requirements and inventory. The next step was analysing state map to identify areas of inefficiencies. The next step entailed the creation of an action plan and implementing it after analysing the future state maps. The last steps were evaluating the benefits expected to ensure that the change expected is attained. According to Hartung (2010), the current state map is collected using information about the actual pathways of information and materials along the whole value stream. The major advantage of using value stream mapping is that it highlights all the areas ina company that are inefficient and highlights each problem on an individual basis. It also allows every problem to be handled individually. Value stream mapping and worksheets were selected over other methods of measurement because they are easy to use, inexpensive and portrays the process of the organization from the beginning to the end of the exercise. Value stream mapping is also easy in documenting transitions from the current value stream to future value streams in an organization hence easy to track any changes in the value chain (Fiore, 2004).The information captured in the value stream would be used to enable the company reduce waste inventory lead-time and improve the overall process in the company.

The other tool that was used in the measurement is the seven waste evaluation tools. The seven wastes are lists of unproductive and non-value adding manufacturing practices which are listed as overproduction, waiting, transportation inappropriate processing, excessive inventory unnecessary

movement and defects (Michael & John, 2004). These are non-value added losses. It entails the use of current states and ideal states of the process or product to minimize and remove waste. It is an easy and inexpensive method of measurement.

Analysing phase of DMAIC is all about evaluating the data obtained from the measurement step to determine where the problems are (Arthur, 2011). From the value stream, mapping the company's problems could be classified into over processing, inefficient layout time wastage and improper utilization of resources. The five whys tool was used in the analysis to evaluate the cause of problems. The five whys is a simple tool that helps companies in getting to the cause of problems. It entails probing the cause of problems through creating a concise and clear problem statement for every step in the process that is problematic (Taylor, 2008).

The Fish bone diagram was also used in the Analysis step. A fish bone diagram is a simple graphic representation that reveals all the possible causes of a problem, cause and effect diagrams shows all the causes of problems simultaneously stimulates problem-solving and displays all the problems clearly and logically (Michael, 2002).

Analysis of the Results

Inefficient layout makes the calculated manufacturing lead-time to be 40.88 minutes for every item

The machine can perform both coatings and curing simultaneously, so it is possible for the two processes to go on simultaneously.

The company meets the monthly demand of the warehouse at 300 items a month.

Underutilization of human resources since it is possible to reduce the number of shifts in the department.

Improvement phase of DMAIC

Improvement phase is all about effecting the changes to rectify the problems found in the analysis phase. The proposed plans were as follows:

The change	Previous status	The advantage
Combining the set-up machine parameter (1 worker) and preparing the item for the coating (1 worker) at the same time preparing the machine is lunching up (20min)	In the previous setting, the three combined tasks would take an hour. One worker would turn on the machine and wait for 20min for the bulb to warm up. After that: another worker would start the next step of setting up the machine parameter in20min and Then the worker would start preparing the machine which would take from him another 20min	Process time reduced from 1 hour to 20 min Better use of human resource

The change	Previous status	The advantage
While the machine is coating the items, one worker can prepare the items for the second batch The other worker starts to set up the parameter for the second coating	In the original setting, the worker would wait till the coating finishes then they would set up the parameters	The major change here would be the better use of human resource, also in such a way that only three workers would be needed.
Move the packaging department to the cleaning roam	Originally, it was required for the items to be shifted to packaging department and to be packed by another worker there.	Cycle time will change to up 5.2 min/item In addition, there would be a reduction in the number of the workers in this process and another worker in packing department is not required.

In summary, the improvement step was envisioned to reduce the Lead, process time and cycle time and reducing the shifts from 12 to ten per month.

Control Phase

The control phase of the DMAIC process is about ensuring that the gains made in the improvement process are maintained. It is, therefore, necessary to document the procedures and methods using some tools and making sure that the employees of the organization have the knowledge of communicating project results. Continuous monitoring and evaluation tool should also be created to ensure any problems that arise are addressed. This may include the modification of the process maps to reflect any changes. The project team should also ensure that anyone in the process is trained, and effective communication occurs. The most important step in control is the creation of monitoring and evaluation plan (Arthur, 2011). The tools that could be used in this process are Statistical Control Processes. In closing the control phase, the project team should ensure that it has successfully documented and standardized the new processes created good reference information and trained staff as well as a process of monitoring and evaluation.

Discussion

After analysing the hydraulic process using DMAIC Approaches, the major bottlenecks found in processes were time wastage, the inappropriate layout of the working area and the inappropriate workflows in the organisation. The waiting period before moving from one-step to the other is long and time wasting. The long wait times are because of the inefficient layout of the work processes and long periods taken preparing items for the next steps. The waiting period before the first coating process begins is twenty minutes. The Hydraulic coating process has too many processes and movement of items between the different areas of the room resulting in unnecessary movements. Over-processing of

items caused by double packaging, procedures were also evident. Value stream mapping was very useful in revealing these operational bottlenecks. The proposed improvements made to the hydraulic coating processes were redesigning the work layout plan to follow a U cell layout, streamlining the processes to ensure there was no wastage of time while moving from one-step to the other and merging the hydraulic coating process and packaging to take place in the same area. The execution of these adjustments resulted in a reduction of lead time by 5.2 per item, the process and cycle time also reduced significantly indicating that the Implementation of DMAIC principles was ideal in removing inefficiencies and waste from the process.

Conclusion

The introduction of DMAIC process seems to be a very useful tool in streamlining the process of hydraulic coating in the company. After implementation of DMAIC principles, the lead-time for the products in this process reduced by5.2 minutes per very item. There was a reduction of the number of shifts required for the process from 12 to ten shifts per week. The cycle time for the product also reduced and there was a better use of the human resources at the company. The implementation of DMAIC principles in this company indicates that DMAIC is a powerful tool for eliminating waste and enhancing processes tool within an organisation.

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