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Research Article

A Relevance of Lean Six Sigma in Biomedical Manufacturing Industry: A Future Scope

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Abstract: The Biomedical Engineering Department of the India Health Authority is under tremendous pressure to play a crucial role in providing adequate health services in the nation and improve its performance due to the global epidemiological problem. Most biomedical equipment repair shops in Egypt are struggling to meet the extensive repair schedules while providing functioning medical equipment to the public health system. The aim is to meet the growing demand for biomedical devices that provide first-class services at reasonable prices. Therefore, there is an urgent need to utilize waste reduction and continuous improvement techniques such as Lean Six Sigma (LSS) to rapidly improve the process capacity for the return of repaired devices in the biomedical engineering field. This paper presents a case study on the implementation of Lean Six Sigma methodology in an Indian biomedical device repair shop. A thorough study of the entire process was conducted to improve it and reduce the repair lead time. The results show that Lean Six Sigma can be successfully applied to increase the availability of functional medical devices in India's public hospitals.

Keywords: Lean Six Sigma (LSS), Continuous Improvement, DMAIC, Bio-Medical Instruments, Healthcare, Maintenance

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INTRODUCTION

Medical devices must be handled carefully and effectively from the time of purchase until they are damaged. This concerns the operating procedures, the procurement method and the maintenance rules that are applied in this context. It is a challenge for patients, doctors and the hospital to manage the maintenance of medical equipment. Medical device manufacturers play an important role in public health and the global economy. Moreover, the manufacturing of medical devices is very strictly controlled by regulatory authorities [1]. The medical device industry is one of the most heavily regulated industries. It is subject to laws that govern the safety and performance of devices throughout their life cycle ,while the non-regulated manufacturing industries do not operate under government rules and laws [2]. Consequently, the implementation of continuous improvement methods such as Lean Six Sigma (LSS) in the regulated manufacturing industry differs from the non-regulated manufacturing industry. One of the differences is that the desired changes must be validated and submitted to the authorities for review [3]. Regulated industries, such as manufacturers of pharmaceuticals and medical devices, are subject to the regulations, guidelines or laws of the U.S. Food and Drug Administration (FDA) or, in Europe, the European Medicines Agency (EMA) [4].

Fig:01 Significance of Lean Six Sigma Bio-Medical

The aim is to identify where time is lost in project implementation due to overcoming or complying with regulations. A better understanding of LSS implementation issues in regulated industries could help with project planning and potentially counteract delays by providing contingencies. Using a case study of the implementation of an LSS project in an Irish medical device manufacturing company, the barriers and enablers to implementing LSS in a regulated environment are identified. The LSS implementation in a medical device company will then be compared to the implementation of a similar LSS project in a non-regulated industry to find out.

Lean Six Sigma (LSS):

Lean and Six Sigma(LSS) is a important quality operation and enhancement conception that enables associations to ameliorate their performance(Bhamu, & Sangwan, 2014; Mohan, et al 2022). This approach integrates spare manufacturing with the five phases of Six Sigma DMAIC(Singh, & Rathi, 2021), with the DMAIC methodology furnishing a design for the spare enhancement systems(Tzadok, et al., 2022). When spare manufacturing and Six Sigma are combined, they come more important and overcome the disadvantages of each methodology(Mohan, et al 2022; Zhang, & et al. 2012).

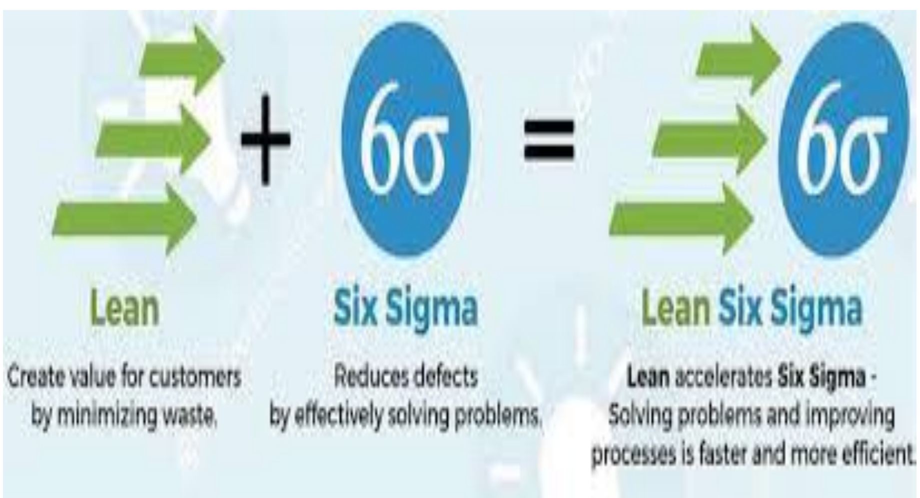

Figure No. 02 Lean Six Sigma in Manufacturing

Lean Six Sigma has proven to be an effective approach for meeting customer needs by reducing manufacturing faults and process variations. Lean Six Sigma is a methodology that aims to achieve the fastest rate of improvement in customer satisfaction, cost, quality, method speed, and invested capital in order to maximize shareholder value. [5].

Objectives of the Study:

The traditional literature review process is not the same as the Systematic Literature Review (SLR). As shown in Fig. 1, it is a thorough procedure that involves a comprehensive exploration of the literature. In their 2003 study paper, Tranfield, Denyer, and Smart made the initial introduction to it [12]. SLR is completed in three stages. The review is planned in the first phase, and after a few inclusion criteria have been established, the review is carried out in the second phase. In the third phase, the papers are finally reviewed [13]. There is a criterion to search for the articles that is mostly focused on the issue connected to the implications of the lean six sigma methodology, the LSS framework in the healthcare industry, and how to include/exclude the articles. In addition, the language used in the articles is taken into account when determining whether or not to include them.

So, for the current study, hundred and forty articles were analyzed but some of them were extruded due to the following barriers:

Language of the article (means articles must be only in English).

Article must have the concept of lean six sigma.

Article must be on healthcare sector.

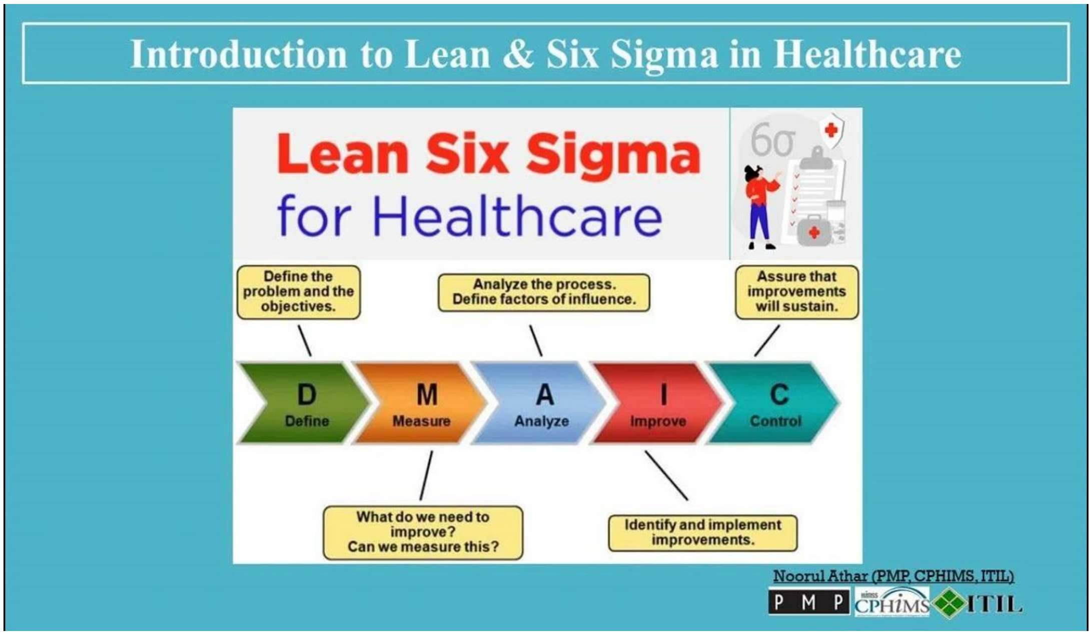

Figure No. 03 Introduction to Lean & Six in Health Care

This research articles may be distinguished based on three primary attributes: location, study category, and time. Place represents the nation that is the subject of the research investigation. A nation can fall into one of two categories: developed or developing. On the other hand, the research category refers to the kind of article or methodology the article uses. The four categories of research that fall under this category are conceptual, descriptive, empirical, and exploratory. Conceptual research is the development of hypotheses and ideas through observation. It is often not necessary to conduct experimentation in order to introduce a new concept or improve an existing process [14]. On the other hand, a descriptive research study encompasses any significant advancement, modifications, or events related to the topic being studied within the project's purview [15]. Surveys are used to gather data, which makes it clear that the research scholars have no control over the data they receive and that the study is entirely guided by it. An empirical research study is more of an experimental study that gathers data using observational approaches and then conducts experiments to confirm the findings [16]. An exploratory study, on the other hand, attempts to tackle a novel issue or one for which a solution has not yet been found or is only being developed. An improved understanding of the area or the development of methodologies that could lead to a solution is two benefits of exploratory study [17]. The year the study was carried out or published is indicated by the time.

Systematic literature review of LSS in healthcare

Medical assistance is a type of service, and the healthcare industry falls under this category. It is imperative that the healthcare system be thoroughly modernized with respect to both productivity and efficiency. Since the healthcare system affects everyone's life, it is more than just a business. It took about ten years for the healthcare industry to adopt the Lean methodology, developed by John Krafcik in 1988, and the Six Sigma (SS) methodology, presented by Bill Smith in 1986 [18In the early days, very few research studies were carried out for the Lean and SS in healthcare.

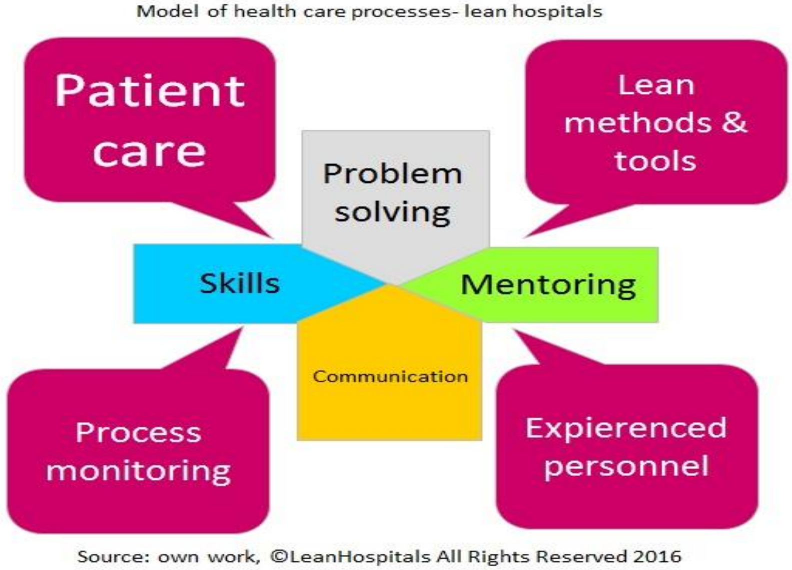

Figure No. 04 Typical Patient Care Process in Bio-Medical Engineering

For example, Usha Manjunath et al. 2007 [21] adopted the LSS approach in an Indian hospital, and Giovanni Improta et al. 2019 [22] implemented the same methodology.LSS to shorten hospital stays for patients in India, as seen in table 1. The evolution of a field greatly benefits from research studies that concentrate on evaluating the literature, as they provide a comprehensive picture of the field's general accomplishments as well as the areas that still require further investigation. Analogously, research has been done to examine the body of literature pertaining to the healthcare industry.

Peimbert García et al. 2019 [23] is one example. A carried out a review and pointed the research academics in the direction of the healthcare areas that needed greater attention. However, the academics have also concentrated on subjects that facilitate the application of LSS in the healthcare industry. For example, V. Vaishnavi et al. 2020 [24] found 16 readiness parameters for the application of LSS in the healthcare industry. A healthcare organization should meet these requirements before beginning the LSS deployment phase[96]. A few important variables that impact the application of LSS are as follows:
Every firm has certain procedures that, in order to be as productive as possible, need to be continuously updated and cared for. Efforts must be directed appropriately in order to guarantee increased output, optimal costs, and reduced waste. Over time, cumulative waste may be filtered out of manufacturing organizations by using Lean Six Sigma principles at every level. The Lean Six Sigma methodology's approved measurements maintain the system's health and allow it to adapt to new requirements. Lean Sigma is a supplement for manufacturing facility to stay healthy with minimal overheads and wastage.

History of Lean Six Sigma in Manufacturing:
In Japan, this approach to production was commonly referred to as the Toyota production system. Womack and Jones (1990) did not classify it as "Lean Production and Lean thinking" until 1986. John Krafick (1988) coined the word "Lean" to refer to Toyota's innovative production methods.
Krafcik concluded, *"The system needs less of everything to create a given amount of value, so let's call it Lean."*

Significance of Lean Six Sigma in Medical Device Manufacturing
Companies must reduce needless spending. There are always going to be new obstacles to overcome in a forthcoming endeavor. A system that is more autonomous, process-oriented, and evolving is required. Reducing wasteful manufacturing activities increases output and productivity.
Lean manufacturing is a technique used to reduce wasteful spending, errors, and rework in the product development cycle. Numerous historical examples demonstrate how well it has maintained the system's dynamic, adaptable, and productive nature.

Problem Statement
The COVID-19 supply chain issues caused a delay in some of our consignment deliveries. The overall landscape of electronic medical device manufacturing was impacted by shortages of semiconductors, Collibri (T-20 & VF-50), SMPS Transformer parts, and Sheet metal parts due to O2 and N2 scarcity. · Transportation delays caused by frequent border seals affected the material/product reach to the required zones. The supplies took a lot longer than normal, and the delivery took a lot longer.

Actions taken to resolve the Issue:
We implemented multiple strategies to enable prompt consignment deliveries.
Prioritization of pre-planning and inventory management based on the clients' project criticality. Managing component obsolescence to guarantee that the design's utilized components remain affordable and simple to obtain Locate and verify suppliers worldwide to guarantee uninterrupted supply

in the event of an unexpected raw material shortage. Make sure that all parties involved communicate clearly and promptly in order to establish and meet reasonable expectations.

Outcome: The turnaround time for the end customers was reduced. Our Global Clientele portfolio expanded rapidly. Retained our clients and delivered consignments within the stipulated timelines. Lean Six Sigma : Components to

Remove: Defective Products

Lean six sigma manufacturing requires that product errors be reduced over time.

Overproduction : The sales team frequently provides an inaccurate estimate of what is to come. In situations like these, production is frequently higher than necessary. Unmovable inventory requires room and frequently causes a backlog.

Holding Out : Customers frequently have lead delays. Knowing where things are going is essential. Realistic thinking produces greater clarity and saves time.

Underutilized Skills: Optimize the ratio of work to employees. It's critical to maintain objectivity while estimating the number of workers needed to do the job. Maintain human resource efficiency through optimal use and ongoing training.

Excessive Processing: It seems reasonable to strive for doing more than is necessary. However, there are times when it can backfire in the manufacturing of medical devices. Over processing raises expenses and ultimately defeats the objective.

Methodology

DMAIC: As illustrated in (Figure 1), DMAIC is a potent six sigma approach that represents the five phases D - Define, M - Measure, A - Analyse, I - Improve, and C - Control. It is a data-driven approach used in many different industries, such as the manufacturing and service sectors. DMAIC is a method for solving problems that is intended to evaluate, find, and fix process inefficiencies in order to improve and enhance the current goods or services and increase customer satisfaction.

Define: Determining the project structure and outlining the general workflow and workspace constitute the first stage in the DMAIC methodology. The first step of the process involves choosing the project champion and moving on to assigning duties to each team member.

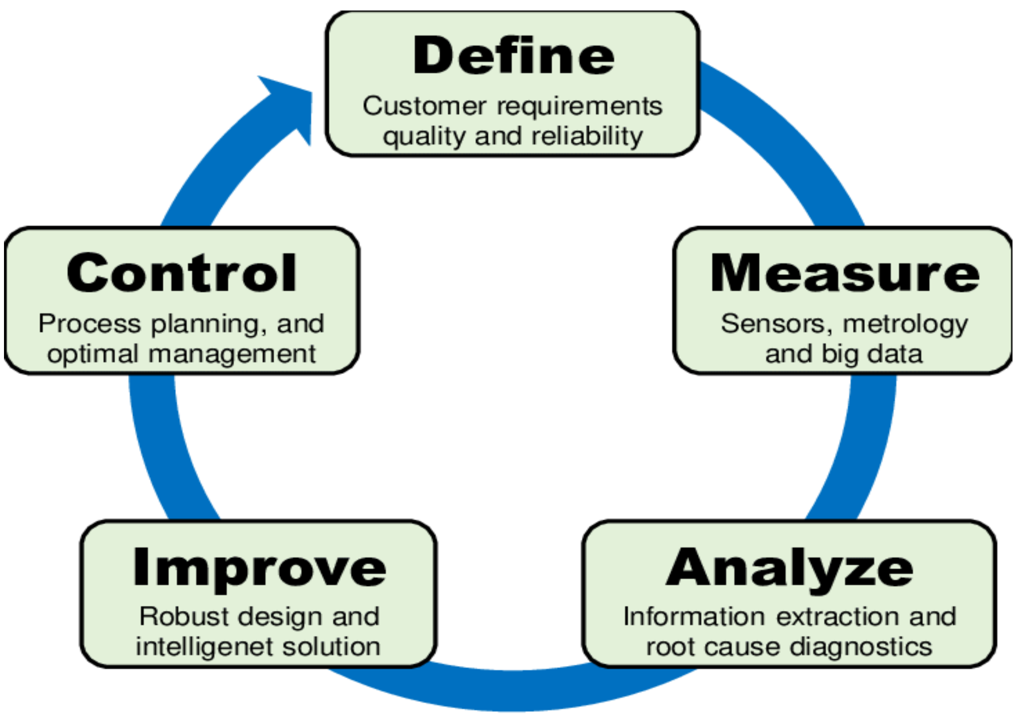

Figure No. 04 Lean Six Sigma DMAIC Process cycle

There are numerous tools available to recognise the following components. Determining the issue, the project's scope, the purpose of the project, the roles of the project teams, process mapping, stakeholder identification, project communication strategy, gathering feedback

Measure: The measuring phase offers a framework for identifying the measurements that will identify the aspects of the issue that require improvement. As a result, a data collecting strategy—such as the critical-to-quality, SIPOC, and data collection plan methods—is essential for measuring the project's parameters and variables.

Analyse: The process's identified variables and parameters are prepared for analysis in order to identify the main cause of the issue and any additional contributing elements. To find all potential trouble spots, inefficiencies, flaws, and shortfalls, failure mode and effect analysis (FMEA), a fishbone diagram, and the five whys approach can be used**.**

Improve: This is the process of determining the best solution, ranking the best solutions, and putting the best solutions into action. To increase process performance, it entails designing, modifying, and improving the process.Measure: The measuring phase offers a framework for identifying the measurements that will identify the aspects of the issue that require improvement. For this reason, a data collecting strategy—such as a data collection plan, critical-to-quality, or SIPOC method—is essential to measuring project parameters and variables.

Analyse: The process's identified variables and parameters are prepared for analysis in order to identify the main cause of the issue and any additional contributing elements. Consequently, it is possible to discover all potential issue areas, inefficiencies, flaws, and problems by applying a fishbone diagram, the five whys approach, and failure mode and effect analysis (FMEA).

Control: The DMAIC approach's final stage. In order to guarantee that the suggested improvement plan is properly carried out and regulated, this step is carried out following the improvement phase. To guarantee achieving the required quality level and gauging the new process capability, a controlled strategy is developed.

Conclusion

This study provided evidence of how Lean six sigma was effectively applied to shorten medical device repair times in Indian public health system. Long-term and labour-intensive, Lean Six Sigma (LSS) ensures an appropriate problem-solving strategy for the maintenance process. To evaluate the present status of the repair procedure, a sizable data collection sheet was made to gather all the measured data for medical equipment. The process of completing documentation for functional devices has the greatest RPN, according to FMEA results. The adopted solution involved replacing outdated procedures for documenting each sub-process in the repair centre with an online system.

In addition, the follow-up procedures changed to computerized techniques. As a result, the stage of completing documentation was removed, which has the most impact on prolonging the total repair procedure. This experiment demonstrated the effectiveness of incorporating LSS and the PDCA cycle throughout the control phase to ensure ongoing progress.

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