ORIENTAL JOURNAL OF CHEMISTRY
An International Open Access, Peer Reviewed Research Journal
www.orientjchem.org
ISSN: 0970-020 X
CODEN: OJCHEG
2024, Vol. 40, No.(5):
Pg. 1415-1425

A Six Sigma Approach to Pharmaceutical Industry- A Better Insight

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http://dx.doi.org/10.13005/ojc/400525

(Received: June 07, 2024; Accepted: September 19, 2024)

ABSTRACT

Six Sigma is a statistical method assists in systemic issue definition, offers tools for monitoring and analysing influencing elements, and suggests changes that are simple to execute. The present study set out to investigate how the pharmaceutical industry's performance changed because of applying six sigma and its methodology demands a strong commitment from top management as well as appropriate training for vital people, also known to as champions and black belts. The article discusses the impact that Six Sigma implementation has on the operations of the pharmaceutical industry and highlights the advantages that organisations as well as consumers might experience because of the findings while also conducting a comparative analysis of the performance of the pharmaceutical industry across various International Organization, before and after the implementation of the methodology. According to the study's outcomes, the performance of the pharmaceutical business is significantly and beneficially impacted by the 6 σ approach.

Keywords: Six Sigma, Process Improvement, Quality by Design, Total Quality Management.

INTRODUCTION

Six Sigma is a statistical concept that is used to systematically outline complications, give methods for measuring and identifying influential elements, and provide changes that are simple to apply. Since Motorola adopted it in the middle of the 1980s, it has developed into an effective tool for leadership with the goal of achieving a quality level of 99.99996%[1]. The quality management tool can serve as a vision, a philosophy, a symbol, a statistic, a target, or a methodology. It simply denotes a standard of excellence that seeks for close perfection. The Six Sigma approach includes a strong emphasis on a very significant improvement where client preferences are transformed into quality improvement operations in the company. The objective that the business aims to accomplish is 3.4 defects per million probable challenges. This process can gradually raise the level of quality towards zero defects and zero failure rate. It is a very structured procedure that concentrates on producing Near Perfect goods and services. It is founded on the three concepts of Process Improvement, Process Design, & Process Redesign and Process administration. Six Sigma quality will

probably replace the present two to three sigma standards for pharmaceuticals in the future, with an objective of 3.4 defects per million chances. This goal involves a defect reduction from 30% to 0.0003%. Although the electronic, communication, and automotive sectors have made Six Sigma a quality aim for, the pharmaceutical industry rarely adopts it. It is important to create quality management systems for maintaining efficiency in the healthcare sector since mistakes might seriously injure people[2]. Consumers and patients, however, demand medications of six-sigma quality with little chance of shortages or recalls. We suggest that six sigma, which means that no more than 3.4 errors occur per million chances, will be the standard for pharmaceutical quality in the future. We talk about the steps needed to get there, such as the importance of the economy, performance-based regulation, QbD, modern manufacturing technology, continuous improvement, and operational excellence. The following article defines a determined objective & seeks to encourage perception despite the difficult route to get there. This objective has been set because it is best for patients and consumers and can be achieved with continuous scientific and technological advancements and investments. Six Sigma initiatives should concentrate on core processes that deliver fundamental products to external or internal consumers and are chosen based on their ability to influence organisational objectives. The ultimate goal of pharmaceutical quality has long been envisioned: a pharmaceutical manufacturing sector that is highly efficient, flexible, and adaptable that consistently delivers high-quality medications without a lot of regulatory scrutiny. By utilising the most cutting-edge digital technologies and applying them to the reduction of inefficient resource usage and non-optimized service operations, the Six Sigma concept aims to achieve this[2].

Six Sigma adoption in the pharmaceutical sector: the reason and advantages

The pharmaceutical sector adopts the Six Sigma methodology often for a number of reasons. It assures continual improvement, risk minimization, adherence to strict guidelines, and quality assurance. Product quality and safety are very important in strictly controlled company operations. The pharmaceutical industry may manufacture reliable, superior goods that satisfy customers' needs and regulatory requirements with the use of Six Sigma methodology.

Pharmaceutical product manufacturing and distribution are subject to tight regulations set by regulatory organisations like the FDA in the US. In order to assist businesses, adhere to these standards, Six Sigma offers a disciplined approach to process improvement and documentation. It focuses on identifying and minimising the potential of manufacturing process errors, which assists in preventing quality problems and product recalls. Another advantage of Six Sigma is cost savings since it eliminates mistakes and defects[3], which results in benefits in areas like waste reduction, decreased rework costs, and improved operational efficiency. It encourages staff to detect and resolve procedural errors and inefficiency, establishing a culture of continuous improvement inside pharmaceutical organisations. To guarantee product consistency and safety, data-driven decision-making is essential. Another advantage of Six Sigma is that it helps businesses offer goods that consistently meet or exceed customers' expectations.

In addition to these advantages, Six Sigma may be used in research and development (R&D) to improve trial plans, quicken the drug development procedure, and lower the amount of time and resources needed to bring new medications to market. Standardised quality management practices are advantageous for globalisation as well.

In an effort to reduce cycle time and costs, a few pharmaceutical companies have lately started utilising Six Sigma[4].

Common misconceptions and myths about 6 σ include: that it primarily applies to manufacturing environments; that it ignores customer requirements; that it is modified Total Quality Management; it uses complicated statistics; it is merely training; and that it is a "magic pill" that requires little effort. In order to achieve the outcomes that businesses require, it should be highlighted that 6 σ actively integrates people, processes, and outcomes in a rigorous, flexible manner. Regardless of sector,

product, or service where 6 σ is used, tangible outcomes must be shown[4]. Comparing the Six Sigma management approach to earlier process improvement programmes like TQM and CQI, the former is more significant. The Six Sigma process covers measurable financial outcomes, combines sophisticated data analysis tools, and employs project management techniques and instruments[5,6].

Scope

The scope of Six Sigma shown in Figure 1.

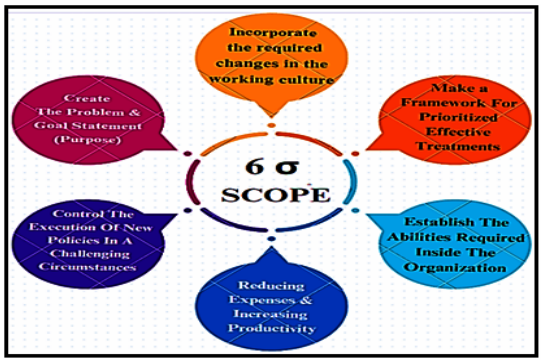

Fig. 1. Scope of Six Sigma[7,8]

Principle of 6 σ[9,10]

Focus On Customer's Requirement or Needs

The Six Sigma process focuses on customers' requirements, In order to define the quality of a product or service. Six Sigma initiatives are started with these principles in mind because businesses must assess quality standards the same way that customers do. The quality of the goods or services is enhanced by this strategy.

Identifying Exact Problem

Data collecting is important for understanding the working process. This involves interacting with them, watching them, and asking questions until they give an adequate response. Understanding the objective and the type of data to be gathered is crucial prior to data collection. After gathering the data, analyse it to see if it offers the essential insights; if not, collect more data.

Reducing Variation And Teamwork

The goal of the Six Sigma process standardisation technique is to get consistent outputs using defined input phases. Standardisation facilitates fewer deviations and more productive outputs. Team members need to find the core reason and fix it to get rid of deviations. These people carry out initiatives and bring out modifications, shown in Figure 2.

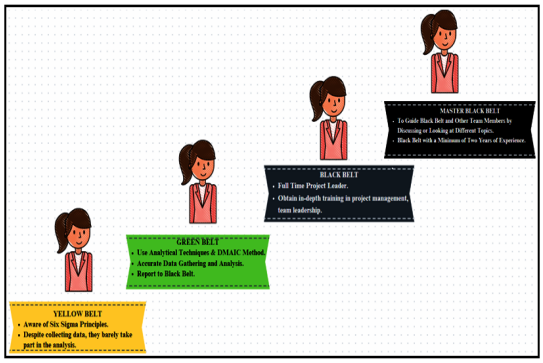

Fig. 2. Six Sigma Certification[10]

Flexible and Structured Approach

Six Sigma develops an organised and adaptable strategy for process improvement over time. DMAIC (Define, Measure, Analyse, Improve, and Control) is a comprehensive advancement process. The DMAIC cycle offers techniques for reducing variation at each level.

Methods of 6 σ

A process improvement system called DMAIC (Define, Measure, Analyse, Improve & Control) is used to enhance processes[12]. The DMAIC process, also known as define, measure, analyse, improve, and control, includes determining the problem that you've decided to address, assessing the present approaches, selecting and implementing a solution, and maintaining that solution going forward[12]. The comparison of two methods shown in Figure 3.

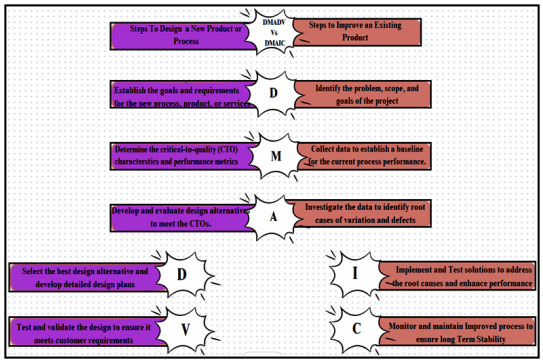

Fig. 3. Comparison between DMADV and DMAIC[13]

Lean Six Sigma

LSS is the collaborative force of Lean and Six Sigma (6 σ), those are crucial business methods for raising an organisation's standard and output. LSS is a basic approach used to identify & eliminate errors & malfunctions within an organisation by focusing on procedure execution features that are truly fundamental

to quality (Singh and Rathi, 2019: 622)[15]. Lean is a tool used by business organisations to simplify production and manufacturing processes, similar to Six Sigma. Lean manufacturing places a strong emphasis on eliminating inconvenient and unnecessary operations from the production process in order to focus only on those that directly improve the outcome[15].

- Lean provides techniques for increasing efficiency, by enhancing value, decreasing waste, and boosting flow.
- Reviews value from the viewpoint of the consumer.
- Lean emphasises end-to-end improvement.
- Reduces lead times, space requirements, and inventories[15].
- LSS certification Shown in Figure 4[10,16]

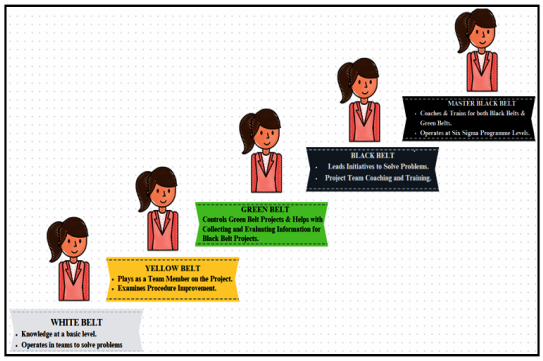

Fig. 4. LSS Certification[10,16]

Comparison of lean and 6 σ

6 σ and lean management are two ideas that have parallel techniques and technologies. Despite sharing a Japanese influence, the two programmes are distinct from one another. While Six Sigma focuses on eliminating defects and lowering variation, Lean management is concerned with eliminating waste using a set of tried-and-true standardised tools and processes that target organisational efficiency while incorporating a performance improvement system used by everyone. Both methods are data-driven, but Six Sigma is significantly more based on reliable data[17,18]. The Comparison Between Lean, 6 σ and Lean Six Sigma given in Figure 5[19,20].

The most effective strategy is undoubtedly Lean Six Sigma. However, just as "there is not a single treatment for all ills," there is also not a single solution to the issues that organisations face on a regular basis. Because of this, businesses are implementing both of these techniques in order to locate the fundamental causes of their issues and solve them by applying the best available toolkits. Six Sigma and Lean Six Sigma are therefore two aspects of the same concept, it could be stated[19].

The Quality Managements Tools: 5S, Kaizen, Lean, Sigma, DFSS

The four quality management tools 5S, Kaizen, Lean, Sigma, DFSS represented in Figure 6.[29]

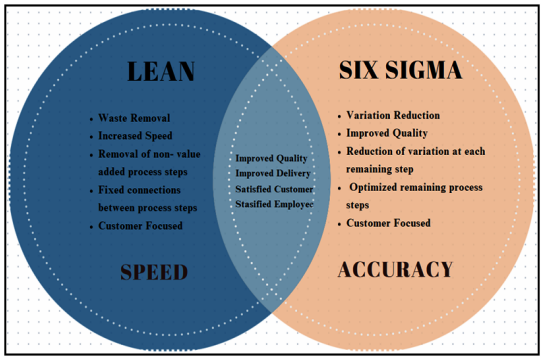

Fig. 5. A Comparison Between Lean, 6 σ and Lean Six Sigma[19,20]

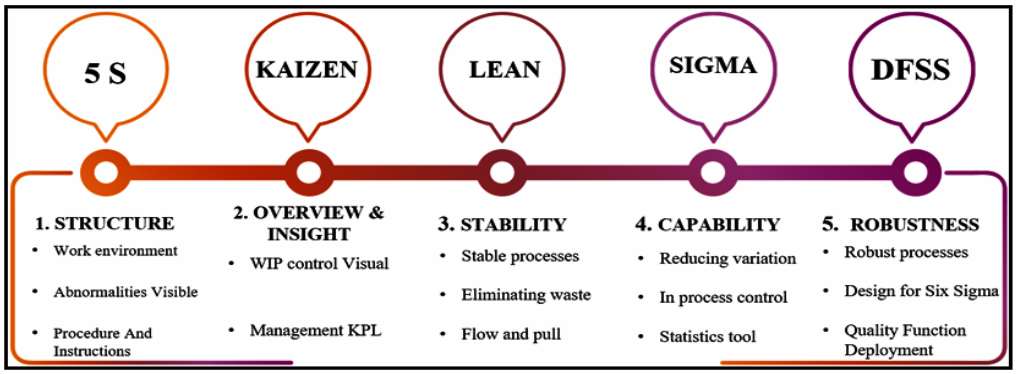

Fig 6. 5S Vs KAIZEN Vs LEAN Vs SIGMA Vs DFSS

Implementation of 6 σ

By using Six Sigma principles, the pharmaceutical sector may improve its production process. By removing errors, these technologies simplify the procedure for staff members to comprehend it. They also contribute to risk management and quality control. Assessing performance at the final stage of the production process is made easier by the Six Sigma methodology. It contributes to the pharmaceutical companies efforts to

- shorten production cycle times,
- enhance processes continuously,
- encourage automated processes[21].

The following are some key reasons why six sigma must be implemented in pharmaceutical companies[22-24]:

By modifying current clinical trial procedures and starting to utilise six sigma methodology

- ➢ To address problems, concentrate on integrating technology and streamlining workflow.
- ➢ By launching new businesses that are not achievable through in-house process improvement
- ➢ Tested research methodologies are used to conduct subjective clinical development studies.

Only a few healthcare organisations comprise over 300 participants organisations of the ISSSP, according to Liu (2005). This shows that the healthcare sector still retains a lot to acquire from Six Sigma and could benefit a lot from different sectors, most of them have effectively employed Six Sigma to accomplish their business goals. Examples include Baxter, Eli Lilly, Johnson & Johnson, and Novartis, highlighting that the healthcare sector still has a lot to acquire from other sectors[25].

Implementing the Six Sigma concept combined with lean management systems is very crucial for dealing with the Structure of a fluctuating & unpredictable market in times of crisis. In conditions of stressful situations, the use of these two coupled concepts, six sigma and lean management, will be essential[21]. Two often implemented approaches to continued growth are lean and Six Sigma. While Six Sigma intends to create constant predictable process outputs by lowering variability and errors, Lean concentrates on providing services and goods quicker, less costly, and more effectively. Toyota Production System established lean in the 1970s, and Motorola Research Centre popularised it in the middle of the 1980s. Both techniques attempt to enhance processes, however, 6 σ believes that lowering process variance could enhance corporate performance while lean believes that eliminating waste will assist in speeding up the process[26]. Fig. 7. illustrates how the five lean principles and 6 σ DMAIC interact[26].

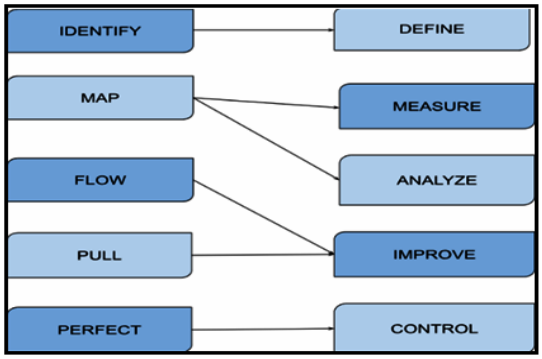

Fig. 7. Interaction of five lean principles and 6 σ DMAIC

Modified Lean and 6 σ Approach

However, because of growing market pressures and competition, more and more pharmaceutical businesses are starting to implement process optimization techniques that have been proven successful in other sectors, such as Six-Sigma and lean manufacturing[27]. The steps are shown in Figure 8[26].

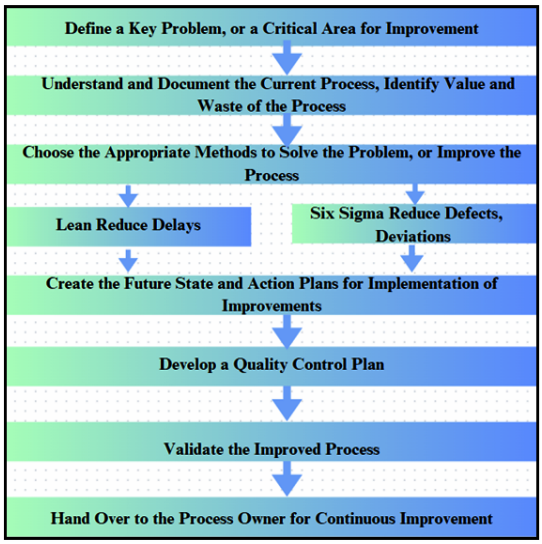

Fig. 8. Modified Lean and Six Sigma Approach[26]

According to Klefsjö and Bergman (2004), organisations that have used 6 σ include GE, Siemens, Nokia, American Express, and Volvo[25]. They noted and said that using Lean

Sigma techniques will lessen the economic load and accelerate the marketing of goods. According to (Dufton, 2009), Pfizer has adopted LSS in the production sector and has experienced a decrease of fifty percent in lead time. Teva has enhanced production by 31%, had 3 production incidents decline by 55%, and has had a 41% total variation drop[28]. An overview of the growth of Six Sigma adoption by organisations from 1987 to 1999 shown in Figure 9[25].

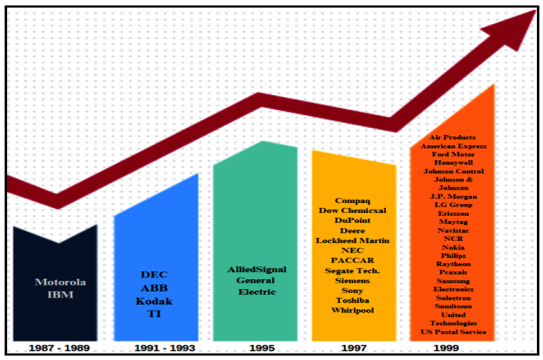

Fig. 9. An overview of the growth of Six Sigma adoption by organisations from 1987 to 1999[25]

Implementation of 6 σ in european pharmaceutical sector

The use of 6 σ in the European pharmaceutical sector entails an organised approach to process improvement, defect reduction, and raising overall pharmaceutical product quality.

The European pharmaceutical business has implemented Six Sigma to comply with legal requirements, promote operational effectiveness, and assure the superior safety and quality of its products. Guidelines for pharmaceutical quality, safety, and efficacy are determined by the European Medicines Agency. To achieve conformity Six Sigma implementation should follow these recommendations[30,31].

Case Study

An International Pharmaceutical Firm with a significant share of the market in Europe, Astra Zeneca, started a Six Sigma journey to improve its production methods and provide the greatest possible quality of the product.

Table 1: Phases and their Objectives

Phases	Objectives
Define Phase	Astra Zeneca started by noticing a crucial problem with tablet coating, one of their production processes. High tablet weight fluctuation was the problem, which might raise issues with quality and regulation. Defining the issue and how it affects product quality was the goal of this phase.
Measure Phase	The company gathered a lot of information on tablet coating procedures, including information on variations in tablet weight, equipment settings, external factors, and operator behaviour. This stage intended to precisely determine the problem's scope.
Analyse Phase	AstraZeneca discovered the underlying reasons for variations in tablet weight using statistical methods. It was found that operators used various ways to modify parameters and that the equipment's specifications were not adjusted. The issue was additionally triggered by variations in the surrounding environment.
Improve Phase	The business made adjustments in response to its findings. It established specific operational processes, standardised equipment settings, and operated under tighter control over the environment. The aim was to lower the range of tablet weights.
Control Phase	Following the modifications, AstraZeneca maintained a close watch on the tablet coating procedure to make sure the modifications were persistent. In order to avoid the issue occurring again, control charts and proceeding measuring methods were also built.

Current scenario of 6 σ in UK pharmaceutical industry

Manufacturers in the pharmaceutical sector implement 6 σ or lean Six Sigma to save operating costs, improve processes, and guarantee they deliver excellent customer service.

Case Study

How Glaxosmithkline Reduced Manufacturing Time By Implementing The Six Sigma Strategy.

The second-largest pharmaceutical firm in the world, Glaxo Smith Kline, with headquarters in the UK, uses 6 σ as one of its methods to a wide range of various jobs in a number of divisions to enhance operational effectiveness[29].

Businesses, like GSK, may implement process improvement strategies that concentrate on producing almost perfect goods and processes by minimising defects according to the Lean Six Sigma approach. Lean Six Sigma, for instance, may

enhance research and development activities, shorten cycle times (reduce manufacturing time for a certain product from 120 days to 30 days), boost sales and marketing campaigns, and lower manufacturing costs and procedures while maintaining profitability in the pharmaceutical industry[29].

At GSK, all three studies were employed simultaneously:

- Lean Six Sigma was producing significant, measurable improvements to the company in GMS (Global manufacturing and supply); In the consumer healthcare sector, project management was significantly enhancing the project performance; and
- Throughout the Organisation, (Organisational Development) teams were promoting increased degrees of participation and successful initiatives for change[34].

None of the three subjects, however, were adequate to carry out GSK's strong ambition on their own. Lean Six Sigma, for instance, was capable of delivering savings and efficiency but struggled to change the general mindset via training alone. However, a strictly OD strategy carried the potential of neglecting direct, observable business indicators and outcomes in favour of building skill and behaviours[34].

Case Study: How Johnson & Johnson Implements The 6 σ Process For Organisational Success[33]

Maintaining sales, profits, and adherence in an extremely competitive international environment is a huge challenge for the pharmaceutical sector. To continually evaluate, review, and improve all business processes, Johnson & Johnson launched an internal "Process Excellence" programme. In order to achieve significant achievement in market share, operational speed, and decreased business expenses, the programme intended to determine key areas for development.

Johnson & Johnson uses dashboard measures, 6 σ, Lean, and Design Excellence to address improvement as more pharmaceutical companies see the advantages of these methodologies. Design Excellence proactively applies these concepts to structure and progression forms, whereas 6 σ actively reduces variability and Lean actively reduces waste. However, when they work together, they become much more effective.

Case Study: Implementing 6 σ In A Functional Organisation To Address Tablet Breakage Complaints

A seven-step internal problem-solving framework that integrates Lean and Six Sigma tools and based on the D, M, A, I, C approach[35].

Table 2: Steps With Their Implementation Within Organisation[35]

Steps	Within organization
Loss Identification	There are 11.6 days of WIP since the packaging department has been recognised as a bottleneck. Short pauses that are caused by product entrapment or sensor triggers are categorised as chronic stops because of their frequent occurrence and impact on production line delay. The backlogged tasks in the packing department, high repetitions, and delayed manufacturing are all a result of these problems. However, the team is still unaware of what is causing these problems. Availability, performance, and quality are the key performance indicators for the team. The packaging division typically produces 5.4 million blisters each week, which is 1.1 million blisters less than what the Purchaser wants.
Loss Stratification	Due to diverse manufacturing settings and equipment, the tablet feed problem was not seen on 3 packing lines. The six blister lines came into focus next when shortstops associated with tablet feed were seen on each of the six blister lines. It implies an extensive problem that needs immediate attention to avoid product delays. Issues on all lines may be resolved by using the lessons obtained from successfully resolving a problem on one line, demonstrating the necessity for correcting problems on all lines.
Project selection	The problem statement was established and assessed, and the results showed that tablet feed problems are the main reason for layoff in the packing area line. These problems resulted in 335 hours of downtime during the period of 4 months, or an average of 20 hours per week, with packaging line C80/2 accounting for 72 hours of that layoff.
Team creation	The team for a "Focused Improvement" project was appointed based on their expertise, problem-solving abilities, and understanding of the subject. To keep everyone on the team informed, a

	weekly oversight system was developed.	
	To provide assurance that production line equipment and technical analysis were comprehended, process technicians, engineers, and operators were involved.	
Problem-Solving	The study team ran product 10C821 on the C80/2 packaging process throughout each shift, doing a check sheet exercise.	
Approach	The most common reason for stoppages was found to be broken, half-finished pills. But if a half table enters the feed channel, it has a tendency to spin 90° and will face longitudinally, obstructing the feed chute.	
	The final stage of manufacturing is the packing section, where inspection is made to make sure the end result is in accordance.	
	There were 751 errors discovered, of which 50% came from the coating section or occurred during delivery to the storehouse.	
	The research found that the majority of tablet breakage happened in the packaging process, with the feed bowl A and top hopper regions accounting for 70% of these incidents.	
	Increasing the hardness of tablets is a simple way to stop them from breaking, aligning with Six Sigma techniques to find the true source of tablet breakage online	
Benefits Realisation	The following steps were carried out as soon as the root cause process was finished:	
and Results	Operations	Causes
	Perform diasorting Trial on riddle plate.	Removal of 79% of damaged tablets discovered during the packing process is possible.
	Accomplish the maintenance check, install the appropriate plattens, and assign storage spaces.	Half-tablet defects cannot be properly removed by using incorrect-sized plattens. No space exists to keep plattens to facilitate switching over.
	Accept storing of plattens to facilitate switching between different-sized tablets.	The existing system is ineffective. Cross-line sharing of platters. Mixing up sets
	Keep the packing line transportation system's variables consistent.	There are no established standards. Standard optimised settings will minimise setup output variance and increase the output quality of manufacturing.
Benefits:	84% less product was backlogged for packing.	
	8.3% more cycles were completed for each batch.	
	25% less time was required to change lines.	
	By 11% more lines were available.	
Roll out and Share	Since the effervescent department has a similar procedure, the project's measures are being evaluated for implementation in the effervescent department throughout the production plant.	

Current Scenario in Indian Pharmaceutical Industry

According to (Karwande *et al.,* 2018) Indian pharmaceutical companies have combined R & D and formulation to attain sustainable development among multinational corporations (MNCs) in the industry. The most usual demands in the private sector involve enhancing human resources, enhancing the standard of work, and upgrading the level of service, customer satisfaction, cost savings, lead times, and experimental testing of products. This has created a competitive component, with major multinational pharmaceutical firms concentrating on improving effectiveness, maintaining GMP, and meeting consumer demand. In R & D, engineering, and production, lean approaches, procedures, and product improvements have been simplified, leading to a 50% gain in cost-effectiveness and output[28].

According to (Patel, n.d.) In order to promote healthy competition amongst Indian businesses and appreciate the huge revenue and program time differences, the Lean Six Sigma Team wants a number of organisations in India to adopt Six Sigma DMAIC methodology[28].

According to (Zhang (corresponding *et al.,* 2012) For drugs or legal problems, large or small enterprises, and specialised sectors with minor modifications as required by consumer demand, Lean Six Sigma has proven beneficial. Financial effectiveness is a barrier, hence study of Lean Six Sigma integration in the SME sector is advised[28].

According to (Al-Shourah and Alzu'bi, 2018) Although humans have long been aware of the existence of Six Sigmas, they have only recently begun to hunt. According to recent Six Sigma publications, the long record has alleviated scientists' doubts and increased practical engagement in many ways. In a number of ways, the Six Sigma phenomenon answered the concerns of scientists[28].

Indian pharmaceutical businesses are increasingly emphasising on implementing complete management solutions that improve output and enhance the company as a whole. Still, there is a long way to go before Six Sigma is widely applied in India[36].

Eli Lilly[36]

One of the few pharmaceutical firms in India that implement 6 σ to improve the efficiency and error-free of their operations is Eli Lilly. Currently, the company is working on two lean Six Sigma initiatives to assist it in detecting non-value added (NVA) and eliminating it to become more efficient and customer-focused.

Zydus Cadila[36]

Zydus Cadila is now planning to introduce Kaizen, a strategy for improving quality, into its manufacturing facility. The staff in Gujarat is in charge of quality assurance and control, guaranteeing the best standard of goods. When machinery is delivered to the factory, it must pass rigorous testing.

1. Inspection on-site
2. Installation Qualification (IQ)
3. Qualification for Installation (IQ)
4. Qualification for Performance (PQ)

To prevent any manufacturing failure, procedures undergo FMEA (Failure Mode Effective Action). SOPs regulate every process in the factory, and quality assurance is in charge of document control.

Dr. Reddy Laboratories Limited

Dr. Reddy's project Rachna aims to automate new product development procedures with Microsoft Accelerator for 6 σ. This assists the business in making crucial choices that will enable it to introduce the best items into the market at the correct moment. Additionally, this has made it possible for the business to recognize possibilities and create new goods that meet those demands rapidly[36].

Dr. Reddy's, Granules India Ltd, Divis Laboratories, Aurobindo Pharma, and Natco all used the five-sigma technique to improve production and achieve a considerable turnover in a single year[32].

With the use of digital technology, data analytics, and lean six sigma methods, Dr. Reddy's are expanding their production capabilities. With every aspect of production and supply chain, Operational Excellence Plan aims to elevate operations above the worldwide top quartile performance. Among their executives, 50% hold Green Belt certifications in Lean Six Sigma[37].

Pfizer[36]

To fulfil its Global Manufacturing Mission, Pfizer has embraced a strategic tool called RFT, to revolutionise the company's operations in terms of quality, regulatory compliance assurance, customer service, and cost reduction. When procedures are executed precisely as intended on the initial attempt, RFT is achieved.

Barriers for implementation of 6 σ

A significant barrier to implementing Six Sigma is the need for more resources and inadequate mentoring and training. Appropriate training is the key to effectively adopting 6 σ. The identification and elimination of such barriers promotes the implementation of 6 σ[38]. The main barriers are listed below in Figure 10[39].

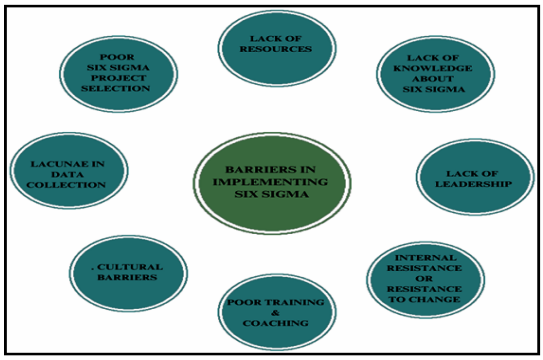

Fig. 10. Barriers For Implementation Of 6 σ

CONCLUSION

6 σ is a statistical approach that methodically explains issues, offers techniques for quantifying and identifying significant components, and suggests small adjustments. The Six Sigma methodology prioritises substantial enhancement, converting customer requests into activities that enhance quality. 6 σ adoption in the pharmaceutical business seems improbable given the significance of quality management systems in the healthcare sector. Patients and customers, however, require

6 σ grade pharmaceuticals with little possibility of shortages or recalls. LSS is a collaborative approach between Lean and 6 σ, which are essential business techniques for improving the quality and productivity of organisations. Lean is a tool used by businesses to simplify production and manufacturing processes, like 6 σ. Lean manufacturing places a strong emphasis on eliminating inconvenient and unnecessary operations from the production process to focus only on those that directly improve the outcome. In times of crisis, combining Six Sigma and Lean management systems is crucial for dealing with fluctuating and unpredictable markets. In the pharmaceutical sector, implementing Six Sigma principles can improve production processes, simplify procedures, contribute to risk management and quality control, and facilitate performance assessment at the final stage of the production process. Indian pharmaceutical companies are increasingly focusing on implementing complete management solutions that improve output and enhance the company. Many case studies of implementing Six Sigma and other Quality Management tools over different countries mainly, UK, European and Indian Pharmaceuticals are shown in the article Along with barriers that Restricts the Application of 6 σ In Organizations.

ACKNOWLEDGEMENT

We would like to express our sincere gratitude to all those who have contributed to the development and completion of this review article. First and foremost, we thank our academic and professional colleagues for their invaluable insights, constructive feedback, and encouragement throughout this process. We are deeply appreciative of the support provided by our institution, Amity Institute of Pharmacy, which has facilitated access to essential resources and provided a conducive environment for research.

We also extend our heartfelt thanks to the experts and practitioners in the field of Six Sigma who generously shared their experiences and knowledge, thereby enriching the depth and quality of our review. Their practical insights have been instrumental in shaping the practical implications and recommendations of this article.

Additionally, we acknowledge the contributions of our peer reviewers, whose critical evaluations and suggestions have greatly improved the clarity, rigor, and comprehensiveness of our manuscript.

Thank you to everyone who has been a part of this journey. Your contributions have been invaluable, and we are deeply grateful for your support.

Conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this review article. No funding was received for this work, and the authors have no financial, personal, or professional relationships that could be perceived as influencing the content or conclusions of this manuscript. All authors have approved the manuscript and agree with its submission to Oriental Journal of Chemistry.

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