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AN OVERVIEW OF SIX SIGMA: IMPLEMENTATION OF SIX SIGMA FOR CONTINUOUS IMPROVEMENT IN THE PHARMACEUTICAL SECTOR

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ABSTRACT

The pharmaceutical industry is one of the most regulated in the healthcare industry, specializing in the discovery, development, and manufacturing of novel, life-saving medications. However, it has its own set of difficulties as it navigates stringent laws, sophisticated production procedures, and its aim of constant development. With rising competitive markets, the pharmaceutical industries are embracing process improvement strategies to stay competitive in their sectors. Among these strategies, Six Sigma has emerged as a promising and evolutionary method adapted by the pharmaceutical industry to improve pharmaceutical quality and reduce defects. Six Sigma is based on a combination of the principles of quality assurance, and quality control by analysing the data. The Six Sigma methodologies DMADV and DMAIC have become increasingly essential within the pharmaceutical industry because of their capacity to attain a precision level of 99.997%, demonstrating their significance in ensuring high accuracy and efficiency in operations. This review explores the implementation of Six Sigma for continuous improvement in the pharmaceutical sector and the future implication of Six Sigma in regulatory affairs, highlighting its importance in ensuring compliance with changing regulations, enhancing regulatory submission, and driving continuous improvement in the regulatory landscape.

Keywords: Pharmaceutical sector, continuous improvement, Six sigma, DMADV, DMAIC, Regulatory

INTRODUCTION

In the highly regulated and complex environment of the pharmaceutical sector, quality, effectiveness, and safety are crucial. An organization must adapt and follow established laws, rules, and regulations, such as FDA standards or GMP, to stay in compliance with standards. Failure to comply leads to untoward outcomes such as penalties, lawsuits, product recalls, production halts, harm to one's reputation, and delayed product launches. Such failure is known as noncompliance **[1]**.

Deviations from Good Manufacturing Practices (GMP) in manufacturing processes can lead to regulatory proceedings, such as a 483, warning letter, consent decree in the US, revocation of manufacturing authorization in Europe, or import prohibitions. These actions can cause significant production disruptions and a loss of manufacturing capacity. Pharmaceutical manufacturers can be severely impacted by regulatory non-compliance **[2]**.

In recent years, the adoption of Six Sigma and continuous improvement methodologies has gained significant attention as a means to enhance operational excellence, ensure product quality, and drive continuous advancements in pharmaceutical processes. Regulatory non-compliance is a critical aspect of pharmaceutical operations. Implementing Six Sigma methodologies to tackle regulatory non-compliance is a strategic approach that has gained attention due to its potential to enhance quality control, mitigate risks, and ensure adherence to stringent regulatory standards **[1]**.

SIX-SIGMA CONCEPT

Six Sigma, a continuous improvement methodology, aims to minimize defects in processes and is often complemented by lean management principles. In pharmaceuticals, it's pivotal to ensure zero-defect, high-quality products that meet safety and efficacy standards. Many companies adopt Six Sigma to enhance efficiency in design, manufacturing, and cost reduction. This combined approach uplifts overall quality within the pharmaceutical sector while maintaining cost-effectiveness. Utilizing Six Sigma in pharmaceuticals serves as a critical tool for scrutinizing failures and rectifying errors, which is crucial for enhancing customer satisfaction and cost reduction. Its integration is fundamental for pinpointing and mitigating flaws within pharmaceutical processes, reinforcing its significance in elevating industry standards **[3]**.

Six Sigma represents a statistical concept and quality management strategy that evaluates the defects within a process or product, aiming for a standard of perfection at the six-sigma level. This statistical approach aids in understanding and managing variability to ensure consistency and quality of outcomes. Six Sigma methodologies include DMAIC and DMADV. These methodologies seek to enhance process performance quality through the identification and eradication of core causes of quality defects. Six Sigma offers resources to assist companies in meeting this requirement. Pharmaceutical companies are using Six Sigma to reduce operating costs and improve customer service **[4, 5]**.

There are various sigma levels with respective percentage defects. Six Sigma can achieve its 99.997% product quality with just 3.4 defects per million operations, as demonstrated by scientific research. This is described in detail in **Table 1**, and its graphical representation is given in **Figure 1** **[6]**.

Table 1: Six sigma levels and its percentage defects

Sigma level	Defects per million	Defects %
1	691500	30.8
2	308770	69.1
3	66811	93.3
4	6210	99.4
5	233	99.98
6	3.4	99.997

HISTORY OF SIX SIGMA

The evolution of Six Sigma represents a transformative journey that has redefined the landscape of quality management and process optimization. From its inception as a quality improvement methodology pioneered by Motorola in the 1980s to its widespread adoption by industry giants like General Electric, Six Sigma has traversed decades, evolving, adapting, and shaping organizational strategies worldwide. The **Figure 1** provides an overview of the historical evolution of Six Sigma.

Implementing Six Sigma within the pharmaceutical sector demands meticulous attention to defining customers, a task that diverges from conventional industry standards. In pharmaceuticals, while patients represent end-users, multiple third-party stakeholders also play pivotal roles.

The actual customers encompass physicians prescribing medications, pharmacists selecting specific medicines, and governments overseeing healthcare systems. Several pharmaceutical and medical device companies, including Baxter, Eli Lilly, Johnson & Johnson, Novartis, and GlaxoSmithKline, have successfully integrated Six Sigma into their corporate strategies. Interestingly, only a handful of these firms are affiliated with the International Society for Six Sigma Professionals (ISSSP) **[4, 7, 8, 9]**.

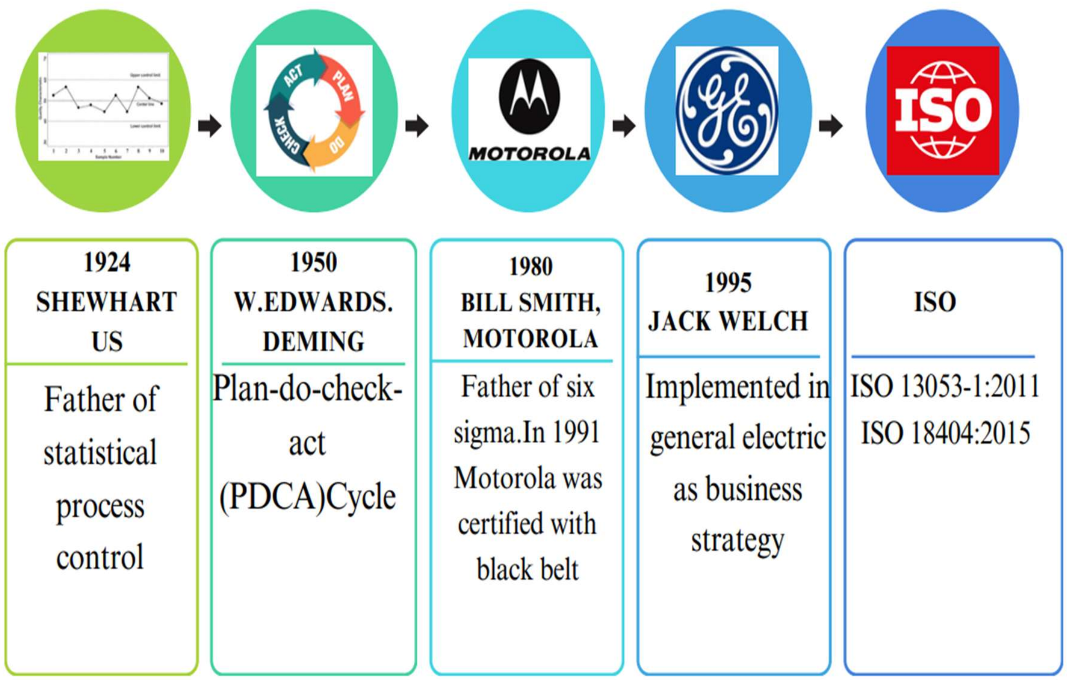

Figure 1: The evolution of six sigma

SIX SIGMA OBJECTIVES

The four main objectives for the adaptation of six-sigma methodologies in the pharmaceutical industry are:

1. **Customer Satisfaction**: Aims to align processes with customer requirements, ensuring higher satisfaction levels by delivering products or services that meet or exceed expectations. Within regulatory compliance, bodies like the FDA function similarly to customers, establishing the benchmarks and prerequisites for pharmaceutical submissions. Pharmaceutical companies must adhere to these guidelines, akin to meeting customer specifications, to ensure their submissions align with the expectations set by the FDA or similar regulatory authorities. This adherence

ensures compliance with stringent regulatory standards **[9, 10]**.

2. **Cost Reduction**: Seeks to identify and eliminate waste, inefficiencies, and non-value-added activities, leading to cost savings and improved financial performance.
3. **Continuous Improvement**: continuous improvement of the organization by fostering a mindset of ongoing enhancement in processes and outcomes.
4. **Data-Driven Decision Making**: Promotes the use of data analysis and statistical tools to drive informed decision-making, enhancing accuracy and reliability in problem-solving. By accessing data on temperature, humidity, and ingredient interactions, they can make informed decisions on formulation adjustments, ensuring the drug remains stable and effective throughout its shelf life. This data-driven process enhances accuracy in formulation decisions, aligns with regulatory requirements, and ensures patient safety **[10, 11]**.

SIX SIGMA METHODOLOGIES

In process enhancement and product development, Six Sigma methodologies play a pivotal role in driving efficiency and quality. Two fundamental methodologies, DMAIC (Define, Measure, Analyse, Improve, and Control) and DMADV/DFSS (Define, Measure, Analyse, Design, Verify, and Design for Six Sigma), stand as pillars in the Six Sigma framework.

1.DMAIC: DMAIC, a problem-solving methodology, navigates through five key stages. It commences by clearly defining the issue, setting project goals, and developing a comprehensive plan. It measures crucial process metrics, establishing a performance baseline. Following this, data analysis uncovers the root causes of process variations. Implementing improvements based on these findings addresses identified issues, and robust controls are established to maintain and monitor these enhancements.

Define: In this phase, the problem is clearly defined, project goals are set, and a project plan is developed.

Measure: Key process metrics are identified and measured to establish a baseline performance.

Analyse: Data is analysed to identify the root causes of issues or variations within the process.

Improve: Based on analysis, improvements and changes are implemented to address identified issues.

Control: Controls and measures are established to sustain improvements and ensure the process remains within specified limits **[12, 13]**.

The diagrammatic representation of DMAIC is given in **Figure 2**.

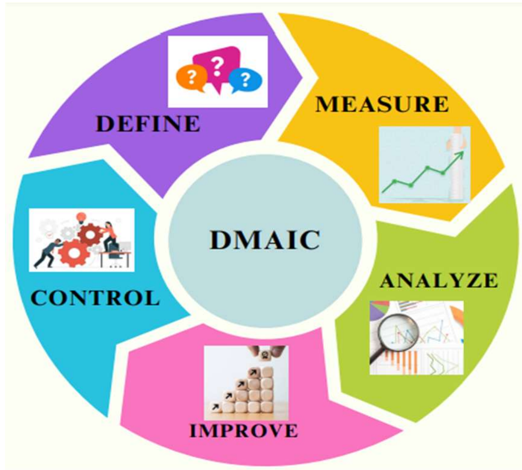

Figure 2: DMAIC Phases

2. DMADV: DMADV aims at crafting new processes or products with minimal defects. It begins by defining project goals and success parameters, followed by identifying and measuring critical components. Analysing the gathered data guides the design of a process aligned with customer needs, striving for minimal defects. The designed process undergoes rigorous verification testing to ensure alignment with established criteria and intended functionality. This is also known as DFSS.

Define: Project goals are defined, and the parameters for success are established.

Measure: Critical components and characteristics are identified and measured.

Analyse: Data is analysed to design a new process that meets customer requirements and minimizes defects.

Design: Based on analysis, a new process or product is designed and developed.

Verify: The new process is verified through testing, ensuring it meets the established criteria and performs as intended **[12, 13]**.

The diagrammatic representation of DMADV is given in **Figure 3**.

Figure 3: DMADV Phases

SIX SIGMA TOOLS

Six Sigma's DMAIC methodology stands as a gold standard. At its core are powerful tools designed to meticulously analyse, refine, and perfect processes. These tools, integrated within the Define, Measure, Analyse, Improve, and Control stages, form the backbone of Six Sigma, driving efficiency and quality in diverse industries.

Effective utilization of analysis tools significantly impacts a firm's productivity and profitability. However, an excessive reliance on these tools can inadvertently hinder problem-solving and improvement efforts. The overemphasis on teaching numerous Six Sigma tools during the introduction phase to organizations emerged as a challenge. Investing substantial time in mastering these tools could lead some Six Sigma black belts to overextend their projects by attempting to apply an exhaustive array of tools. These efforts, as per the study, resulted in frustrating periods that diminished the perceived utility of Six Sigma. As a resolution, we are commencing Six Sigma initiatives with a training program cantered on the most commonly utilized tools. This approach aims to streamline tool proficiency and enhance the practical application of Six Sigma methodologies **[14]**.

Six Sigma is widely applicable in the pharmaceutical business due to its organized methodology and variety of tools. In this industry, where accuracy, reliability, and high standards of quality are critical, Six Sigma instruments are essential resources for guaranteeing the best possible drug research, production, and quality control procedures.

The Ishikawa or Fishbone diagram: It is useful for breaking down and identifying probable reasons for problems in medication development or production. Teams may address core causes and improve overall process efficiency by using this tool, which methodically analyses numerous aspects effecting drug quality or manufacturing inefficiencies.

Control charts: These are powerful tools in the quest to preserve reliable and consistent systems. Strict oversight is required throughout pharmaceutical manufacture to guarantee quality requirements. Control charts help with this by enabling firms to monitor important variables throughout time, guaranteeing consistency and adherence to predetermined guidelines.

Failure Mode and Effects Analysis (FMEA): It is a vital technique for proactive risk management. Pharmaceutical development teams can anticipate risks in the process by carefully assessing possible failure types and their effects. This gives them the ability to create effective risk mitigation strategies, preventing unfavourable consequences and guaranteeing patient safety.

Design of Experiments (DOE): In order to optimize manufacturing parameters or medicine formulations, the Design of Experiments (DOE) approach is essential. Pharmaceutical businesses can enhance medicine efficacy and production efficiency by identifying the most efficient mix of elements by using DOE to systematically test various variables.

Pareto Chart: It provides a way to rank the origins of problems or defects. This instrument helps with important problems that affect the manufacture or quality of drugs in the pharmaceutical industry. Pareto charts allow for focused efforts to improve medicine quality and process efficiency by emphasizing the most important areas for change **[15, 16, 17]**.

Figure 4 below illustrates the application of various Six Sigma tools within each phase of the DMAIC methodology.

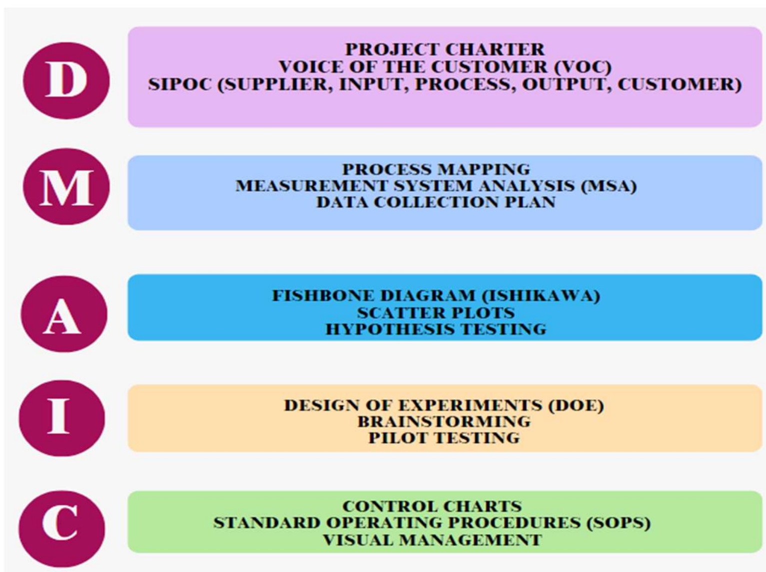

Figure 4: Six Sigma Tools in Each Phase of DMAIC

IMPLEMENTATION OF SIX SIGMA IN THE PHARMACEUTICAL SECTOR

The pharmaceutical industry operates within a stringent regulatory framework, presenting distinct challenges. Regulatory affairs experts play a pivotal role in bridging the gap between industry entities and regulatory bodies like the FDA and guiding the development of new products. Within this landscape, Six Sigma serves as a problem-solving methodology, providing essential principles for managing and minimizing variations. Its applicability extends across diverse sectors, including pharmaceuticals, empowering the transformation of outdated processes into efficient, innovative methodologies **[7]**.

Research and development account for a significant portion of expenses. In this case, it would be advantageous to apply the Six Sigma idea to comprehend the vital procedures involved in developing new drugs, conducting research, and optimizing current ones. These goals are crucial in order to decrease medication failures, maximize resource usage, boost productivity, and make the best use of personnel and other resources. To increase their revenue, a lot of pharmaceutical businesses are trying to change how they operate **[18]**.

Simultaneously, the FDA and other regulatory agencies have concluded that the pharmaceutical business has lagged behind other industries in terms of quality and efficiency. As a result, they have started to support a "quality by design" paradigm rather than the existing "quality by testing." Pharmaceutical manufacturers are to be guided toward consistent and predictable quality (higher sigma's) by the FDA through the PAT (Process Analytical Technology) initiative, a risk-based guidance model, as part of this transformation. The principles of the FDA's PAT initiative are remarkably aligned with lean manufacturing thinking, hinting at a positive outlook for lean practices in the pharmaceutical sector. Notably, companies like Astra Zeneca, Johnson & Johnson, Pfizer, and others have successfully implemented lean methodologies **[19]**.

AstraZeneca is one pharmaceutical company that has used the Six Sigma technique. The company's operations and quality workers were trained to apply DMAIC principles on a daily basis, measuring and improving continuous performance **[20]**.

SIX SIGMA FOR HIGH-QUALITY PHARMACEUTICAL PRODUCTS

Reducing Defects: Six Sigma can identify and eliminate defects in manufacturing processes. By using statistical analysis and data-driven decision-making, pharmaceutical manufacturers can detect the root causes of defects and implement corrective actions to prevent their occurrence.

Controlling Variation: By analysing data and using statistical tools, pharmaceutical manufacturers can identify sources of variation and implement process improvements to reduce them. This results in ensuring that each product meets the required quality standards.

Improving Process Efficiency: Six Sigma helps manufacturing processes by streamlining workflows and eliminating non-value-added activities. By doing so, pharmaceutical manufacturers can achieve higher productivity and cost savings.

Improving Quality Control: Six Sigma places a strong emphasis on the value of ongoing development and quality control. Pharmaceutical manufacturers may make sure that their goods satisfy the necessary quality standards by setting strong quality control strategies in place, performing frequent inspections, and analyzing data using statistical methods.

Customer Satisfaction: Pharmaceutical manufacturers can consistently deliver high-quality products that meet customer expectations by implementing six-sigma methodologies **[21]**.

KEY AREAS OF SIX SIGMA IMPLEMENTATION IN THE PHARMACEUTICAL SECTOR

1. Research and Development: Six Sigma principles can be applied in research and development (R&D) processes to improve efficiency and reduce errors. By streamlining R&D workflows, optimizing experimental design, and implementing data-driven decision-making, pharmaceutical companies can enhance the effectiveness and speed of their R&D efforts **[18]**.

2.Manufacturing Processes: In pharmaceutical manufacturing, Six Sigma serves as a powerful tool to enhance efficiency by minimizing defects and optimizing production processes. Through data analysis, pinpointing the root causes of defects, and implementing strategic improvements, pharmaceutical manufacturers can elevate product quality and operational efficiency **[22, 23]**.

3. Supply Chain Management: Six Sigma can be utilized to optimize supply chain processes in the pharmaceutical industry. By reducing lead times, minimizing inventory levels, and improving supplier performance, pharmaceutical companies can achieve greater efficiency and cost savings in their supply chain operations **[17]**.

4.Regulatory Compliance: Six Sigma can support regulatory compliance efforts in the pharmaceutical industry. By implementing robust quality management systems, risk management processes, and data integrity practices, pharmaceutical companies can align with regulatory requirements and ensure adherence to good manufacturing practices **[2]**.

Here is an example of six-sigma implementation to address a regulatory non-compliance issue in the pharmaceutical industry.

Let’s consider the pharmaceutical company XYZ, which faced repeated instances of non-compliance with GMP in its tablet manufacturing. During the regulatory inspection, it was revealed that the deviations occurred in terms of quality standards, resulting in warnings and potential penalties. Upon analysis, the root cause of the problem was found to be the inconsistency in the process parameters, inadequate training, and poor equipment maintenance. To overcome this, six sigma was implemented, as shown in **Figure 5**.

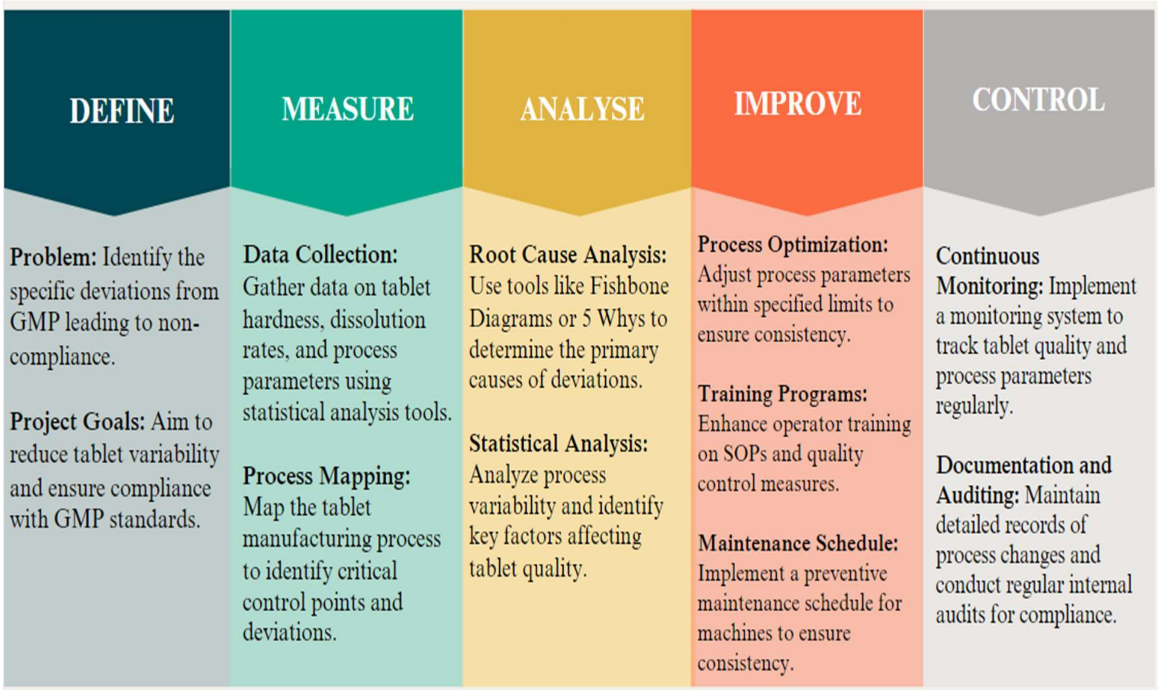

Figure 5: Implementing Six sigma to Address non-compliance

After implementing six-sigma methodologies, regulatory non-compliance can be reduced by continuous improvement in the pharmaceutical sector.

CHALLENGES OF SIX SIGMA:

- Training employees and ensuring they possess the necessary skills in statistical analysis and problem-solving methods can be resource-intensive.
- The investment of time, resources, and costs required to implement and sustain Six Sigma initiatives might be considerable, impacting short-term profitability.
- Sustaining a continuous improvement culture amid the dynamic and ever-evolving pharmaceutical landscape poses a significant challenge.
- Insufficient resources or problems with knowledge in small and medium-sized businesses **[24]**.

SIX SIGMA CERTIFICATION

Six Sigma certification has different levels, representing a structured pathway toward expertise in process improvement methodologies. From foundational understanding to advanced mastery, these signify escalating levels of proficiency in applying statistical tools, problem-solving techniques, and leadership skills within organizational contexts. Six Sigma Certification Levels are shown in **Figure 6 [18, 24, 25]**.

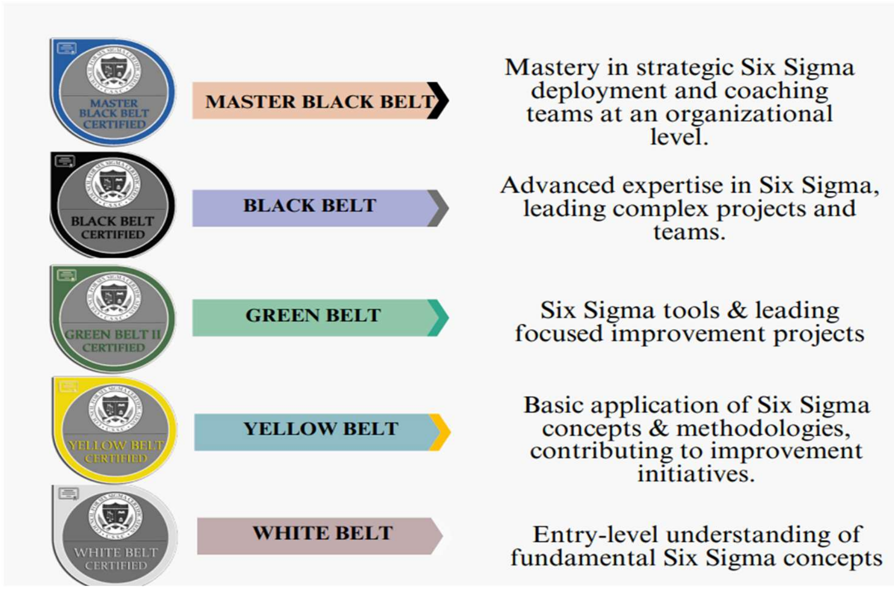

Figure 6: Six Sigma Certification Levels

CONCLUSION

The implementation of Six Sigma in the pharmaceutical sector offers significant potential for continuous improvement, enhanced quality, and regulatory compliance. The pharmaceutical industry operates within a stringent regulatory framework, and Six Sigma serves as a problem-solving methodology that helps manage and minimize variations.

By applying Six Sigma principles, organizations can streamline regulatory processes, reduce errors, and improve overall efficiency. The research and development phase, which accounts for a significant portion of expenses in the pharmaceutical industry, can benefit from Six Sigma methodologies to comprehend vital procedures involved in developing new drugs, conducting research, and optimizing current ones. Regulatory bodies like the FDA have recognized the need for improved quality and efficiency in the pharmaceutical industry. Successful implementation of Six Sigma in the pharmaceutical sector has been observed at companies like AstraZeneca, Johnson & Johnson, and Pfizer.

The future of Six Sigma in the pharmaceutical industry appears promising, with growing recognition of its potential benefits in improving pharmaceutical quality, reducing defects, and optimizing regulatory affairs. Six Sigma can help streamline processes, manage compliance risks, and drive continuous improvement. Its application in regulatory affairs can lead to smoother submission processes, reduced mistakes, and data-driven decision-making. In conclusion, the implementation of Six Sigma in the pharmaceutical sector goes beyond compliance and offers opportunities for continuous improvement, enhanced quality, and regulatory excellence. By embracing Six Sigma methodologies, pharmaceutical companies can enhance their processes, reduce errors, and achieve better outcomes in drug development, manufacturing, and regulatory affairs.

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