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Review Article

Six Sigma in Pharmaceutical Industry – A Comprehensive Review

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ABSTRACT

Strict regulatory frameworks govern the pharmaceutical sector, which demands high standards of quality to guarantee patient safety and effectiveness.In pharmaceutical production, Six Sigma, a data-driven methodology designed to minimize process variation and faults, has become a potent instrument for operational excellence and quality improvement.The use of Six Sigma techniques—DMAIC (Define, Measure, Analyze, Improve, Control) and DMADV (Define,Measure, Analyze, Design,Verify)—as well as their integration with Lean concepts to improve productivity, eliminate the waste, and streamline production processes are reviewed in this thorough study. The study examines the historical evolution of Six Sigma, tracing itsorigins from statistical quality control principles to its widespread adoption in various industries, including pharmaceuticals. Key tools such as Statistical Process Control (SPC), Failure Mode and EffectsAnalysis (FMEA) and Design of Experiments (DOE) are discussed in the context of process improvement and risk management. Additionally, the implementation of Six Sigma in drug development, manufacturing and distribution is analyzed, demonstrating its role in achieving regulatory compliance, minimizing defects, improving cycle times, and reducing operational costs. Additionally, the importance of Six Sigma training and certification—from White Belt to Master Black Belt—is underscored, stressing its influence on workforceadvancement, leadership growth and the culture of continuous improvement in pharmaceutical companies. The analysis highlights the success of Six Sigma in reaching a nearly zero-defect rate (3.4 defects per million opportunities) and its role in sustainable quality management.

INTRODUCTION

Continuous Quality Improvement (CQI), Process Improvement (PI), Quality Assurance (QA), Quality Management (QM) and Re-engineering has been a part of Process improvement since long time. The term Six sigma was coined by a Motorola Engineer, Bill Smith, to describe anew quality control process that emerged from the Total Quality Management (TQM) strategy.

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DMAIC & DMADV are two sub-methodologies of six sigma used for accomplishment for it. The model of DMAIC i.e. Define- Measure- Analyze- Improve – Control has been used to reduce defects, which is the main aim of Six Sigma. The model of DMADV i.e. Define- Measure- Analyze- Design- Verify is an enhancement system applied to develop new processes or products at Six Sigma quality standards. This is further developed to create a robust design in order to meet customer requirements which are the basis of Design for Six Sigma and to explore process and ways to increase efficiency, which is the basis for Lean Six Sigma [1, 2]. As per research data, it has been observed that the implementation of six sigma in any process has resulted in achieving 99.996% accuracy and only 3.4 defects as per million processes. The Six sigma & lean six sigma has been implemented by manufacturers and also applied in pharmaceutical industry to reduce operating costs and provide superior service to their customers [3].

History: [4,5]

Carl Frederick Gauss (1777–1855) is credited for developing a new measurement standard known as Six Sigma. Gauss was the first to introduce the idea of a 'normal distribution'. Six Sigma, as a standard measuring dissimilarity in a product, has first appeared in the 1920s when Walter Stewart showed that three sigma's from the centre of the pattern is the point where correction must prevail. This choice of measurement was rapidly preceded by other criteria measurement. Bill Smith, one of the Motorola engineers popularized the term Six Sigma in the year 1986[4]. Walter A. Shewhart is often regarded as one of the foundational figures in the development of quality control principles that later influenced Six Sigma. While he was not directly involved in Six Sigma (which was formalized later by Motorola in the1980s), his contributions laid the groundwork for many of the concepts that Six Sigma builds upon. Walter Shewhart's contributions provided the scientific basis for modern quality management and continuous improvement methodologies, including Six Sigma. His emphasis on using data and statistical methods to manage and reduce process variation is a fundamental principle that continues to shape Six Sigma practices today. While Six Sigma itself emerged decades after Shewhart's death, his influence remains embedded in the core tools and principles used by Six Sigma practitioners. It was Motorola University that first proposed the six-step method to be followed. Motorola developed the Six Sigma methodology which had its roots in 1980's. The Design for manufacturing training program has been evolved to be a TQM enhancement tool [5].

Principle of lean six Sigma-

Lean-reduce or eliminate the waste (non-value-added processes and procedures).

Six sigma- continuously improve the process.

Lean six sigma- combination of both i.e. to eliminate the waste and continuous improvement

Formula for Defects per Million Opportunities (DPMO)-

$$\text{DPMO} = \frac{\text{Number of defects discovered x 1000000}}{\text{Opportunities per defect}}$$

Learning curve [3]: The Six Sigma level of the Gaussian curve is as given in Figure 1.

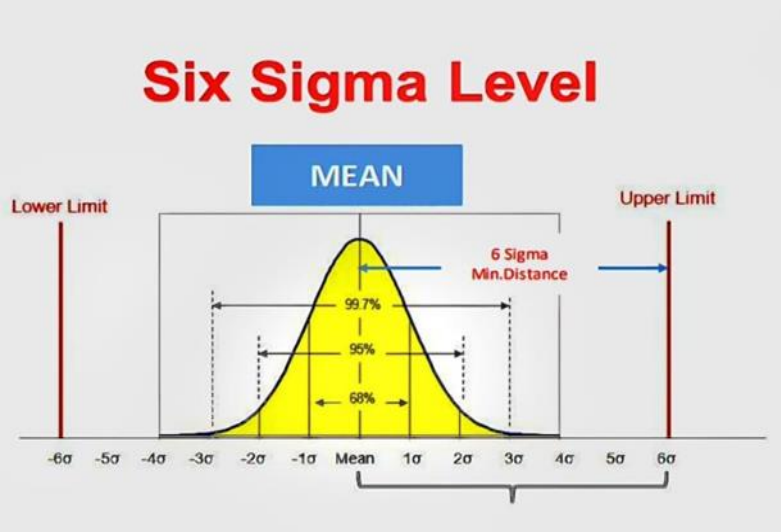

Figure 1: Six Sigma Gaussian Curve

Objectives [6]

The objectives of six sigma methodology have been focused on process of improvement and variation reduction.

Overall Business Improvement- Six Sigma methodology focuses on business improvement. Beyond reducing the number of defects present in any given number of products.

Reduce Defects/Variability- Any business seeking improved number of must reduce the number of defective products or services it produces. Defective products can harm customer satisfaction levels.

Reduce Cost- Reduced costs equal increased profits. A company implementing Six Sigma principles must look to reduce costs wherever it possibly can-without reducing quality.

Improvecycletime- Any reduction in the amount of time it takes to produce a product or perform service means money saved, both in maintenance costs and personnel wages. Additionally, customer satisfaction improves when both retailers and end users receive products sooner than expected. The company that can get a product to its customer faster may win her business.

Increase customer satisfaction - Customer satisfaction depends upon successful resolution of all Six Sigma'sother objectives. But customer satisfaction is an objective all its own.

The other objectives of Six Sigma methodology are as follows [7]:

- Integration of quality on daily basis
- To enhance competitiveness
- To change organizational profile
- To develop organizational Competencies
- Improving end-to-end process management and measurement
- To improve organizational performance
- To develop the bottom-line responsibilities towards the continuous improvement works.

Research and Development in Six Sigma

Six Sigma study uses a qualitative method with descriptive research, and uses analysis in each section so that the subjects studied are authentic. It aims to identify the factors that the cause occurrence of production process rejects, with the aim of reducing rejectsin production process. To

complete this research, the Logbook of company documents related to production and rejects are utilized.Additionally, interviews with production operators in the field are conducted to gather first-hand insights. The primary data source consisted of records from the sterile preparation production process, ensuring that all research data is both relevant and valid. This comprehensive approach guarantees the reliability and accuracy of findings, providing a solid foundation for further analysis and conclusions. [8] The research and development in Six Sigma methodology is the most important process and it is also exceptional in the pharmaceutical industry part of the cost. In research and development of new drug, Six Sigma process want to understand process to reduce medication failure, maximize efficiency, resource use, growth, productivity, efficiency, maximum utilization of employees and other methods.In an industrial environment, DMAIC is focused to solve problems, by improving the manufacturing processes. Therefore, many R&D people will be lost, asking themselves and the Six Sigma experts, how to "adapt" the DMAIC roadmap, to solve problems connected to design rather than to process. The automatic answer is that "anything can be considered a process". A very common decision is to start the program by running training sessions about the DMAIC roadmap, and leave the Design for Six Sigma for the next round, as an upgrade. The rationale behind this decision is clear: first start solving problems (DMAIC), later start avoiding them [9].

Defects [10]

Six Sigma is a methodology that helps companies' eliminate defects and improve business processes, thereby boosting their product's quality and profits. It was developed by Motorola with the aim of achieving fewer defects in parts manufacturing to other aspects of business like sales, marketing, etc. Six Sigma employs a statistical method to measure the defects and improve them. It emphasizes cycle-time improvements while reducing to no more than 3.4 defects per million opportunities. This means that a process is considered to be efficient if it produces less than 3.4 defects per one million products. In practical conditions, a Six Sigma process can produce 99.99966% of opportunities per defects. It's important to think that a defect is a product that failed to meet customer expectations. Trying to reach the Six Sigma level, you have a high probability of producing items that are excellent in the eyes of customers. There are several sigma levels, each of which indicates the number of allowed defects per million, as is shown in the table below.

Sigma performance level from one to Six Sigma

The different levels of sigma performance are given in Table1 [11].

Table 1: Sigma performance levels

Sigma levels	Defect Sper million	Defectin%
1	691462	69%
2	308538	31%
3	66807	6.7%
4	6210	0.67%
5	233	0.023%
6	3.4	0.00034%

DMAI Cand DMADV [13]

DMAIC process (Define, Measure, Analyze, Improve, and Control) is an improvement system for existing processes falling below specification and looking for incremental improvement. DMADV process (Define, Measure, Analyze, Design, Verify) is an improvement process used to develop new processes or products at Six Sigma quality levels. It can also be implemented if a current process requires more than just incremental improvement. Workflow of DMAIC and DMADV given in figure 2.

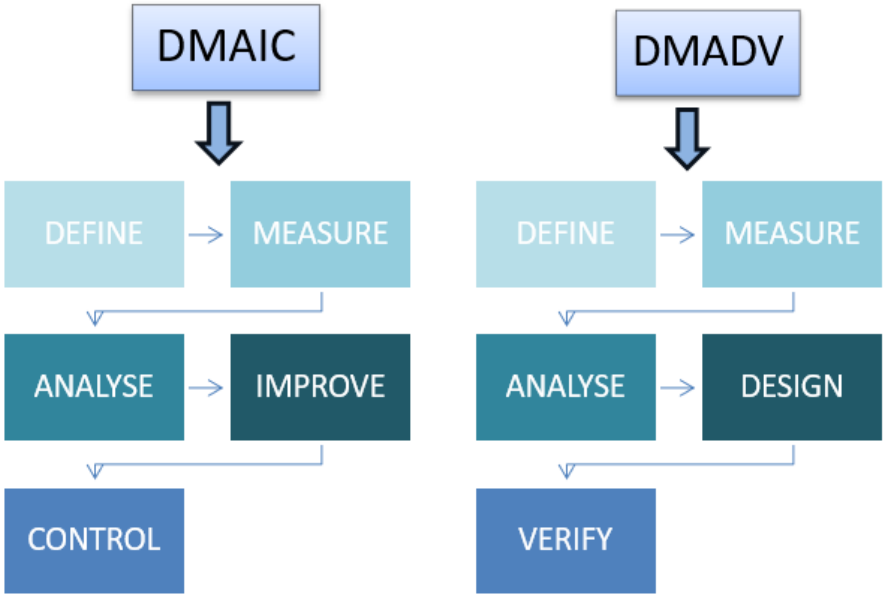

Figure 2: Workflow of DMAIC and DMADV

Similarities of DMAIC and DMADV

The similarities in the methodologies of DMAIC and DMADV are as follows:

- Both Six Sigma methodologies are used to drive defects to less than 3.4 per million opportunities.
- Both Six Sigma methodologies have data intensive solution approaches. (Intuition does not work for Six Sigma - only facts are considered)
- Both Six Sigma methodologies are implemented by Green Belts, Black Belts and Master Black Belts.
- Both Six Sigma methodologies are the ways to help meet the business / financial bottom-line numbers.
- Both Six Sigma methodologies are implemented with the support of a champion and process owner.

Differences between DMAIC and DMADV

Though both the methodologies sound alike but there is huge difference between them

DMAIC-

- D-Definepretensions to ameliorate theoverall process between the company strategy and client's demands
- M- Measure the current processes. Collect applicable data on the current processes andalso use this data as a basis of new unknown comparisons.

- A-Analyze the relationship within the process. To understand the relationship is very important to determine factors that can ensure to keep the company's strategy inline with theguests' demands.
- Improve the process. It's important to constantly ameliorate and optimize the process, using analysis and otherways. One of the many ways that is frequently used is Design of Experiments. (This is a way that can help to test a hypothesis, usingrespectable experimental design)
- C- Control. It is important ensure that you can control and correct anydissonances avoiding conceivablyexpensiveblights and loss of quality.

DMADV-

- D- Define thedesignpretensions to ameliorate the overall process between your company strategy and the client's demands.
- M- Measure thecurrent processes. Collect applicable data on thecurrent processes andalso use this data as a basis of new unknown comparisons.
- •A-Analyze as a basis of new unknown comparisonsrelationship within the process. It's important to understand the relationship to determine factors that caninsure to keep the company's strategy inline with theguests' demands.
- D-Designthedetailedprocesstomeetclientneeds
- V- Verify the design performance and capability to meetclient need.

Crucial Tools and ways Used in Six Sigma [14]

There are many tools and ways used in Sig Sigma. Some of the tools used are as follows:

Statistical Process Control (SPC): A set of tools used to cover and control a process to insure that it operates at its fulleventuality. Control maps are generally used in this area.

Pareto Analysis: This type of Analysis is grounded on the 80/20 rule, which helps identify the most important causes of problems byfastening on the 20 of factors that contribute to 80 of the effects.

Root Cause Analysis (RCA): A system of relating the underpinning causes of problems or blights. Tools like Ishikawa plates, 5 Whys, and Fish bone plates are frequently used for this purpose.

Failure Mode and Effect Analysis (FMEA): A structured approach for relating implicit failures in a process, assessing their impact, and enforcing conduct to all pitfalls.

Design of Experiments (DOE): A statistical system for optimizing processes bytotally changing variables to determine their effect on the outgrowth.

Voice of the Customer (VOC): A process for landing client requirements and rephrasing them into product or service specifications.

Process Mapping: Imaging theway in a process to identify inefficiencies, backups, and areas for enhancement. Flowcharts are generally used tools.[14]

Training and Development [16]:

The Six Sigma courses are advertised at five levels: white belt, yellow belt, green belt, Black belt and Master Black belt as portrayed in Figure 2: [15].

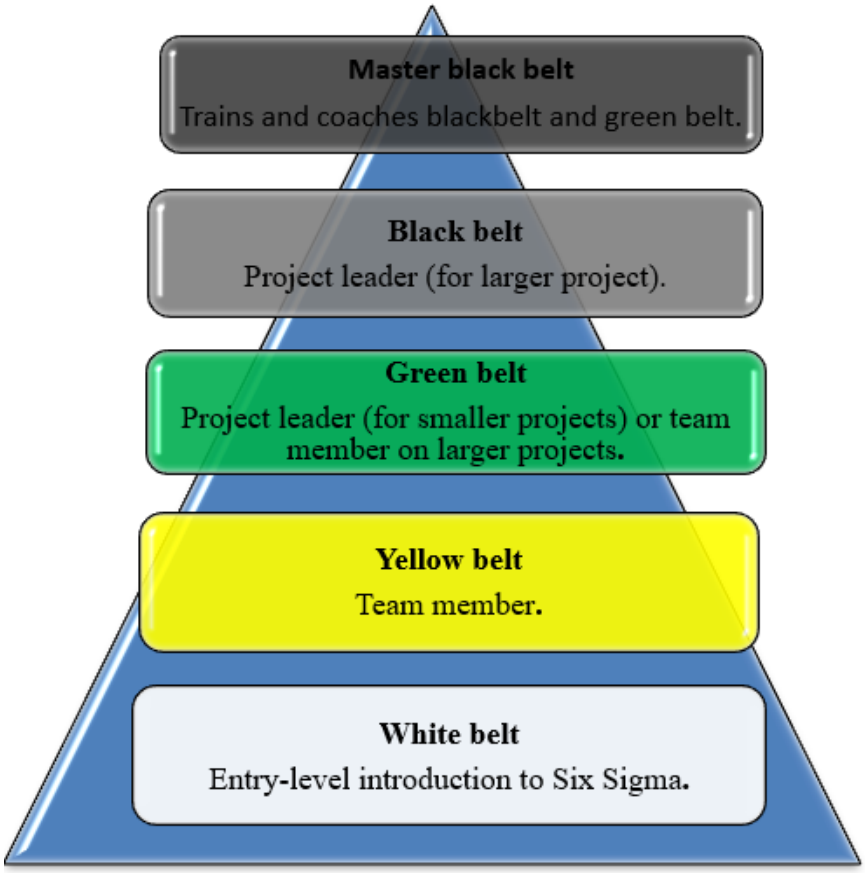

Figure 3: Six Sigma Belt Levels

Six Sigma White Belt: White Belt holders are required to total a few hours of SixSigma preparing on the essentials of Six Sigma. A Six Sigma White Belt is the entry-level certification in the Six Sigma technique, which is a data-driven approach to progressing forms by recognizing and expelling surrenders or wasteful aspects. White Belt certification is ordinarily pointed at people who are modern to Six Sigma and need to learn the fundamental concepts and phrasing.

Six Sigma Yellow Belt: Yellow Belt holders will get 10 to 15hours of preparing, which will provide them adequate information to work in regions such as prepare mapping and information collection.ASix SigmaYellow Belt is an entry-level certification that speaks to a foundational understanding of the Six Sigma strategy, with a center on advancement and quality administration. Whereas the White Belt is regularly for those fair beginning to learn the Six Sigma, the Yellow Belt gives a more profound understanding of how Six Sigma works in hone, especially in back parts.Yellow Belts are regularly included in littler handle change ventures, working nearby Green Belts and Black Belts to help in information collection, problem-solving and prepare investigation.

Six Sigma Green Belt: Green Belt certification is frequently acts as the spine for the venture groups that perform numerous of their day-to-day assignments. Green Belt certification can offer assistance almost 25–50% of their venture group on Six Sigma ventures. A Six Sigma Green Belt is a certification level in the Six Sigma strategy that

shows a more profound understanding of handle change strategies and the capacity to lead littler ventures or be a key group part on bigger ventures. Green Belts are ordinarily more included in the down to earth application of Six Sigma instruments and strategies, and they work on ventures that center on progressing forms and decreasing surrenders or wasteful aspects.

Six Sigma Black Belt: It is a highly skilled professional responsible for leading complex process improvement initiatives within an organization. Black Belts are experts in applying the Six Sigma DMAIC methodology (Define, Measure, Analyze, Improve, Control) to solve business problems, reduce variability, eliminate defects, and improve overall process efficiency. They possess advanced knowledge of statistical analysis, Lean methodologies, and quality management tools, enabling them to conduct data-driven investigations and deliver sustainable improvements. In their role, Black Belts lead cross-functional teams, mentor Green Belts, and collaborate with senior leadership to align projects with strategic objectives. They manage every phase of project execution — from defining the problem to implementing solutions and ensuring control measures are in place to maintain results. Proficient in software like Minitab or JMP, Black Belts interpret complex data sets and transform insights into actionable strategies. Beyond technical expertise, they also demonstrate strong leadership, communication, and change management skills, making them effective change agents within their organizations. Certification as a Six Sigma Black Belt typically requires formal training, the successful completion of one or more real-world projects, and passing a rigorous examination administered by recognized bodies such as ASQ or IASSC. Industries across manufacturing, healthcare, finance, IT, and logistics highly value Six Sigma Black Belts for their ability to deliver measurable financial impact, drive customer satisfaction, and foster a culture of continuous improvement, positioning them as critical assets in today's competitive business environment.

Six Sigma Master Black Belt (MBB): It is the highest level of expertise in the Six Sigma methodology, responsible for the strategic implementation of process improvement across an organization. MBBs play a critical role in designing and overseeing Six Sigma programs, ensuring that initiatives are aligned with the company's long-term goals and driving continuous improvement at the enterprise level. Beyond their mastery of Six Sigma and Lean tools, Master Black Belts possess exceptional leadership, coaching, and mentoring abilities, guiding Black Belts and Green Belts through complex projects. They provide advanced statistical analysis and consulting, offering solutions to the most challenging problems while ensuring that projects deliver measurable, sustainable outcomes. MBBs also work closely with executive leadership to integrate Six Sigma practices into the organization's culture, creating a data-driven decision-making environment and fostering an overall quality-centric approach. Certification as a Master Black Belt requires extensive experience as a Black Belt, completion of a formal MBB training program, and the successful mentoring and certification of other Six Sigma professionals. MBBs are valued for their ability to manage high-level project portfolios, influence corporate strategies, and drive large-scale operational transformations, making them key leaders in organizations focused on achieving world-class performance and operational excellence.

Six sigma in pharmaceutical industry [17, 18 19]:

Six Sigma in the pharmaceutical industry centers on making strides quality, lessening defects and

upgrading effectiveness in drug advancement, formulations and delivery forms. By utilizing data-driven strategies, such as DMAIC, Six Sigma makes a difference distinguish and kill varieties in forms that can lead to item surrenders or wasteful aspects, guaranteeing consistency, compliance with controls (like FDA guidelines), and lessening costs. This approach points to accomplish near-perfect quality (with a target of 3.4 defects per million units) to upgrade understanding security, meet administrative necessities, and move forward by and large commerce execution.

Drug Improvement:

In the sedate improvement stage, Six Sigma methods are utilized to streamline forms, diminish blunders, and progress productivity from disclosure to clinical trials. Key applications incorporate:

Reducing Inconstancy: By utilizing Six Sigma devices like DMAIC, pharmaceutical companies can distinguish sources of changeability in early-stage and clinical trials. This makes a difference in optimizing details and lessening the chances ofdisappointments amid trials.

Improved Decision-Making: Six Sigma centers on collecting and analyzing information to make educated choices, driving to a way better prioritization of medicated candidates. This leads to a more productive allotment of assets amid the R&D stage.

Risk Administration: Six Sigma's accentuation on data-driven decision-making makes a difference recognize potential dangers in sedate improvement, such as detailing disappointments or issues with clinical trial plan. By relieving dangers early, companies can maintain a strategic distance from expensive late-stage.

Manufacturing:

Pharmaceutical fabricating includes exceedingly complex forms, with strict administrative guidelines and noteworthy dangers related with item quality. Six Sigma devices can offer assistance in different zones:

Reducing defects: The essential objective in fabricating is to decrease defects, which might lead to hazardous or ineffectual drugs. Six Sigma centers on decreasing defectsper million openings (DPMO), which straightforwardly interprets to making strides item quality and lessening the probability of reviews or adjust.

Process Control and Optimization: Six Sigma employs factual strategies such as control charts and prepare capability examination to screen and make strides the consistency of the fabricating handle. This leads to higher yields, decreased batch-to-batch inconstancy, and more dependable item yield.

Compliance: Pharmaceutical producers are subject to thorough administrative prerequisites (e.g., FDA controls, GMP rules). Six Sigma makes difference guarantee compliance by making strides traceability, lessening human blunder, and standardizing strategies.For instance, standard operating procedures (SOPs) can be optimized to guarantee adherence to administrative measures.

Lean Fabricating: SixSigma frequently works hand-in-hand with Incline standards to diminish squander (e.g., overabundance stock, downtime, pointless steps in generation) whereas progressing prepare stream and decreasing cycle times. In pharmaceutical production, this can hasten time-to- market for drugs and more proficient utilization of assets.

Distribution:

Once drugs are made, guaranteeing they are conveyed productively and securely is a basic portion of the product.Six Sigma can be connected to coordination and supply chain operations to:

Enhance Effectiveness: Six Sigma apparatuses like esteem stream mapping can be utilized to recognize wasteful aspects in the supply chain, such as delays, abundance dealing with, orstock outs. Streamlining these forms guarantees opportune conveyance to drug stores and healthcare suppliers.

Improve Traceability and Follow-up: SixSigma makes a difference move forward the traceability of drugs all through the dissemination chain, which is vital for both security and compliance. Upgraded follow-upsguarantee thatdrugs are conveyed to the right areas in the right condition, decreasing the probability of fake drugs entering the supply chain. **Supply Chain Optimization:** By utilizingmeasurable estimating and other Six Sigma methods, pharmaceutical companies can oversee stock levels, diminish lead times, andmove forwardby and large supply chain properly. This can anticipate stock outs, decrease wastage, and guaranteedrugs are accessible when needed.

Application and Benefits

Quality has progressed: Improved quality of items and administrations through Six Sigma hone to an awesome degree. Associations can guarantee that they meet or indeed surpass the desires of the clients by upgrading and centering on cutting abandons. This consideration towards quality increments client fulfillment and leads to giving an association a great notoriety, as well.

Customer fulfillment expanded: Six Sigma is exceptionally noteworthy in building client fulfillment. In expansion, fulfilled clients are more plausible to be rehash clients and suggest the organization and subsequently clear a way for long-term victory.

Improving quality: Six Sigma centers on quality enhancement by methodically recognizing and tending to surrenders, mistakes, and prepare varieties.

Diminished errors: The Six Sigma program diminishes blunders, revamp, and client complaints, which eventually progresses the quality of items and administrations.

Meeting client needs: It increments client fulfillment due to the benefit and items that meet the needs and desires of the clients.

Cost lessening: Six Sigma is broadly utilized to help organizations in sparing costs through deformity end, decreased squander, and optimized forms. It smoothens out the operations and makes them more productive, minimizing pointless costs.

Better Job Opportunities [20]

Acquiring a certification will distinguish you from the employers by proving your special skills in cost reduction, revenue enhancement, leadership, and quality control. Since the Six Sigma skills can be applied to several industries, the more you possess and demonstrate those skills, the higher your chances of getting eligibility for various positions.

Career Advancement into Managerial Roles: The Six Sigma certification process will qualify you to possess management, leadership, risk assessment, finance, and team building skills - highly sought skills in managerial functions. Students pass from one Six Sigma belt level to another to increase their capacity to oversee more significant projects and lead more effective teams.

Higher Wage Expectations: Having Six Sigma certification under your beltallows you to enjoy high salary scales within your job, or qualify for more highly paid jobs. Indeed, this is evidence of your capacity to take up moreresponsibilities and work more productively. Incremental salaries will depend on the level of Six Sigma certification, employer, and location.

Workforce Motivation: Six Sigma allows motivating the employees of the organization by ensuring that they are allowed to use available technology for higher ease of work and saving of time. Employees, when motivated and inspired to work and challenge themselves, become more productive automatically.

Effective Time Management: Six Sigma concentrations, on the other hand, involve efficient business and increased productivity through helping employees make bettertime management. Improved timemanagement ofemployees leadsto good work-life balance, boosting their morale to work smart and harder.

Career Advancement: It puts one above the rest in terms of extra advanced skill sets that the company holds dear. Therefore, Six Sigma certification helps uplift your career and guides you one step ahead of the competition.

Develops Leadership: Training of Six Sigma guidelines develops leadership quality by informing of how methods increase the process revenue and efficiency. Black belt certified professionals or master black belt certified professionals are basically the trainers who train and guide the entry-level quality analyst to grow to make them good leaders. The Six Sigma certification and training open various managerial positions for professionals wishing to make a career in quality and process improvement. Six sigma guidelines help improve the quality of the products and services provided to customers, hence generating a happy and satisfied customer.

CONCLUSION: -

Six Sigma in the pharmaceutical industry focuses on improving quality, reducing defects, and enhancing efficiency in drug development, manufacturing, and distribution processes. A Six Sigma White Belt is a starting point for anyone interested in the Six Sigma methodology. It provides foundational knowledge, which can be expanded as individuals move on to higher level certifications. Yellow Six Sigma is an excellent starting point for those looking to get involved in process improvement initiatives. While Yellow Belt holders don't lead complex projects, their role in supporting Six Sigma initiatives is crucial to ensuring that improvement efforts are successful and sustainable across an organization.For those interested in learning the basics of Six Sigma and contributing to process optimization, Yellow Belt certification is a great first step.The Six Sigma Green Belt is a key certification for professionals who want to take a more active role in process improvement initiatives. It offers a deeper understanding of Six Sigma tools and techniques and prepares individuals to lead small- to medium-scale projects, contribute to larger efforts, and drive efficiency and quality within their organizations.A Six Sigma Black Bel**t** is a prestigious certification that signifies advanced knowledge in process improvement, statistical analysis, and project leadership. Black Belts lead critical, high level projects that drive substantial business improvements. A Six Sigma Master Black Belt represents the pinnacle of Six Sigma expertise. Master Black Belts lead the strategic deployment of Six Sigma across the organization, mentor and guide Black Belts and Green Belts, and ensure that process improvement initiatives are

aligned with business objectives and sustained over time.

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