Journal of Turkish

Operations Management

Enhancing production processes in the medical industry: A six sigma case study with industry 4.0 integration

M. Paşa Gültaş[1*]

[1]Dış Ticaret Bölümü, Doğanşehir VKMYO, Malatya Turgut Özal Üniversitesi Malatya
e-mail: pasagultas@gmail.com ORCID No: https://orcid.org/0000-0003-1215-3509

Article Info

Article History:
Received: 25.11.2023
Revised: 12.04.2024
Accepted: 08.08.2024

Keywords

Six sigma,
Medical industry,
Process analysis,
Industry 4.0

Abstract

This article examines a successful case study of a medical industry company implementing Six Sigma methodologies. Focused on steel-cutting operations, the study utilized the DMAIC approach, revealing a process operating at a sigma level of 3.2. Following rigorous analysis and improvement efforts, the sigma level increased to approximately 4.9, significantly enhancing process quality. The study reduced errors by approximately 90%, leading to substantial improvements in product quality and operational efficiency. Embracing the core principles of the Six Sigma approach and statistical problem-solving techniques, the company aimed for continuous improvement. The initial phase involved meticulously analyzing the existing process and identifying and rectifying errors and defects. Utilizing appropriate statistical tools for data collection and analysis, the study pinpointed root causes and developed improvement strategies. This paper showcases how the Six Sigma approach was successfully implemented in a medical industry company, highlighting the transformative impact on process quality and operational efficiency.

1. Introduction

The medical industry has a vital responsibility to improve and protect human life. It operates in diverse areas seeking to advance healthcare, provide treatment to patients, and cultivate a healthy society (Hoeft et al, 2018). This sector lies at the crossroads of technological advancements, scientific research, and production methods. Despite these ambitious aims, the medical industry confronts major obstacles (Chowdhury et al, 2021).

The intricacy of healthcare services, the delicacy of medical products and services, and the strict mandates of regulations present a formidable challenge for managing the medical industry's operations (Farahani et al, 2018). It's imperative to abide by quality standards, optimize production processes, and minimize errors to ensure the safety and effectiveness of medical products (Obeta et al, 2019). However, accomplishing these objectives isn't always simple. Understanding the critical importance of the Six Sigma approach in the medical industry can help businesses meet challenges and provide more effective and reliable solutions (McDermott et al, 2022, a).

Six Sigma plays a vital role in assisting the medical industry to overcome challenges. Its methodology is centered around excellence and allows businesses to optimize operational processes, with a particular emphasis on important benefits like cost reduction, quality control, and patient safety (Antony et al, 2018). One of the most common challenges in the medical industry is cost reduction, which Six Sigma can aid by improving efficiency (Thakur et al, 2023). Quality control is crucial for producing medical devices and managing hospital processes. The implementation of Six Sigma can have a substantial impact by decreasing process variance and continuously increasing quality standards (Noronha et al, 2023). Patient safety ranks among the top priorities in the medical industry, and the data-driven approach offered by Six Sigma can enhance this essential area by minimizing errors and improving processes (Sharma et al, 2022). These advantages clearly show the potential of using Six Sigma as a strategic tool in the medical sector and how it can improve industry standards.

This paper examines how Six Sigma has been applied and the successes achieved in the medical industry, and explores how it can provide solutions to the challenges facing the industry. It centers on a case study of Six Sigma implementation in the medical industry. The article examines how a medical manufacturing organization resolved a particular issue with its steel cutting procedures, following the systematic application of the Six Sigma methodology and the achieved outcomes. It also underlines the method's potential to boost operational excellence and give a competitive advantage.

In the forthcoming sections of this study, a comprehensive examination shall be undertaken to elucidate the implementation of Six Sigma in the medical industry. This assessment will address unique challenges encountered in the production of medical products and demonstrate how Six Sigma proffers reliable solutions.

2. Six Sigma

Six Sigma is a method of measuring how well a service or production process performs. It uses a sigma value to indicate the process's effectiveness and ability to operate without defects, which are any products or services that fail to meet quality standards. It is important to use precise terminology to ensure clarity and objectivity in measuring process quality. An opportunity is defined as any instance when a product is made or a service is delivered. Achieving a high sigma value is considered optimal performance for the Six Sigma performance level. When a process operates at a 6σ level, it is six standard deviations away from customer specifications. In other words, only an average of 3.4 defects occurs per million products, resulting in a 99.99966% statistically defect-free product output. This level of quality is nearly perfect for any given process (Harry & Stewart, 1988; Binder, 1997; Pyzdek, 2003; O'Connor and Kleyner, 2012; Murumkar et al, 2018; Yusof & Lee, 2022; Sodhi, 2023).

Achieving a sigma level of 6 offers notable cost advantages for businesses by addressing the costs associated with poor quality (Alzoubi et al, 2022). The Six Sigma methodology emphasizes error reduction and elimination of non-value-added processes, leading to significant cost savings (Daniyan et al, 2022). Achieving a sigma level of 6 offers notable cost advantages for businesses by addressing the costs associated with poor quality (Tsung & Wang, 2023). Companies that do not implement Six Sigma often face high and undisclosed costs related to inefficient processes.

Companies operating at the three or four sigma level generally allocate 25 to 40 percent of their revenue towards remedying issues, which is referred to as the cost of quality or more precisely, the cost of poor quality (Marwaha, 2022). Conversely, the Six Sigma methodology, which is focused on quality, carries out a systematic approach through the DMAIC steps, identifying, measuring, analyzing, improving, and ultimately controlling problems step-by-step (Escobar et al, 2022).

Six Sigma Implementation Methods (DMAIC)

Six Sigma is a system that can primarily improve quality and therefore the time management of projects. It has been applied in the manufacturing sector for many years. Since Six Sigma, which consists of a process called DMAIC (Define, Measure, Analyze, Improve and Control), improves time, quality and cost management in projects (Pyzdek, 2003), it has been seen that the Six Sigma method is used in all sectors of finance, health, engineering and construction as well as research and development (Kwak & Anbari, 2006).

An organization using the DMAIC methodology with a Six Sigma strategy can achieve near perfect quality as well as superior availability, reliability, delivery performance and after-sales service (Arnheiter & Maleyeff 2005). Six Sigma focuses on identifying defects in projects and can then create a database to improve the project process.

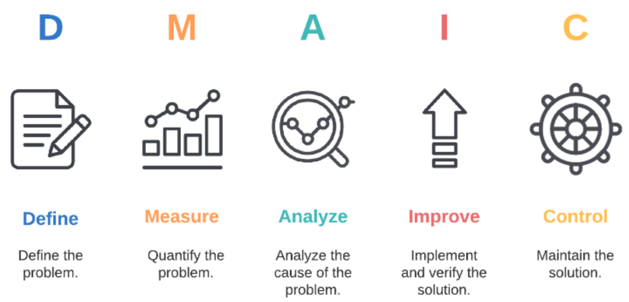

Figure 1. DMAIC Principles

The DMAIC (Define, Measure, Analyze, Improve, Control) steps are the steps that form the basis of the Six Sigma methodology (Figure 1.). These steps provide a guide for solving a problem in a systematic way (Tsung & Wang, 2023). The DMAIC problem solving methodology is particularly useful when the cause of the problem is unknown or uncertain, when there is potential for significant savings, and when the project can be done in 4-6 months, In

Six Sigma and process improvement efforts, the selection of Six Sigma projects is the most vital initial step. Properly selected and well-defined Six Sigma projects lead to better and faster results. Conversely, poorly selected and poorly defined improvement projects lead to delayed results and dissatisfaction (McLemore et al, 2022). In the medical industry, statistical problem-solving techniques and six sigma have various application areas (Sordan et al, 2023). These techniques are frequently used in clinical trials, healthcare development processes, analyzing patient data and quality control processes. In clinical trials, statistical analysis is important to determine the efficacy and side effects of a treatment (Kolluri et al, 2022).

Six Sigma in Medical Industry

In recent years, quality improvement initiatives in the medical industry have gained increasing importance. These efforts aim to enhance the quality of healthcare services and medical products, ensure patient safety, and improve operational excellence (McDermott et al, 2022, b). In this context, there is a body of literature available. For instance, Sim et al. (2022) highlighted the significance of quality improvement processes in designing and manufacturing medical devices. Similarly, a study by Hrgarek and Bowers (2009) examined the applications of Six Sigma methodology in the medical industry and demonstrated its effectiveness in enhancing quality standards.

Regarding quality improvement efforts, the role of the Six Sigma approach in the medical industry is noteworthy. Six Sigma is a data-driven and systematic methodology that achieves defined quality targets (McHugh & Farrell, 2022). This methodology reduces process variation and optimizes quality control processes, enabling businesses to achieve excellence (Parab et al, 2016). Notably, the applications of Six Sigma in the medical industry significantly impact the safety, efficacy, and quality of medical devices (Sim et al, 2019). Researchers provide a series of case studies demonstrating that Six Sigma reduces error rates in healthcare, improves patient outcomes, and enhances operational efficiency (Vadori, 2020).

However, there are specific challenges and barriers to quality improvement efforts. The medical industry is subject to complex regulations and frequently faces rapid technological changes (Maci & Marešová, 2022). These variations can affect quality improvement processes and complicate the determination of strategies to be implemented (Salditt & Bothell, 2004). Additionally, high demand and rapid innovation in the medical industry can further complicate quality improvement processes (El-Haik & Mekki, 2011). Therefore, comprehensive planning, strategic management, and collaboration are required to implement quality improvement efforts effectively (Rathi et al, 2022).

Quality improvement initiatives in the medical industry are critical for enhancing the quality of healthcare services and optimizing operational efficiency (Sodhi, 2020). These initiatives underscore Six Sigma methodology and similar quality improvement approaches. Future research should explore new methods and strategies for further development and improvement of quality improvement processes in the medical industry.

3. Methodology

In this section, a Six Sigma case study conducted in a manufacturing organization producing medical diagnostic kits is presented. Challenges such as improving consecutive quality control processes, eliminating errors in production, and increasing efficiency by analyzing data were addressed.

3.1. Define Phase

The Define phase aims to thoroughly understand the problem in the steel cutting processes of the medical manufacturing organization, supported by data analysis, and to set goals (Singh & Rathi, 2023). In this stage, the current situation was better understood by supporting the problem with concrete data, aiming to reveal the measurable dimension of the problem.

Production processes, along with the intermediate and final products, were examined in this phase. Specifically, problems related to faulty processes during cutting and issues with chip waste after cutting were identified (Singh et al, 2023). It was observed that these problems disrupted production and led to additional quality control processes. Due to the organization being in the medical industry, there was little tolerance for errors. Therefore, even slightly defective products were either destroyed or reproduced. To address this, the number of quality control employees was increased from 9 to 15 to prevent errors. However, this also meant an increase in costs at some point.

***Problem Statement*:** Quality issues have been identified in steel-cutting operations. These issues manifest as increased defective products and post-cutting waste and defects. As a measurable metric, the number of defective products, specific cutting stages and parameters where defective products occur, and the amount and type of post-cutting waste (e.g., chips, surface defects) have been identified. The impact of these issues on the business has been assessed, identifying adverse effects on key performance indicators such as operational efficiency, product quality, cost-effectiveness, and customer satisfaction.

***Significance of the Problem*:** The impact of these quality issues on the business is significant. The increasing number of defective products reduces customer satisfaction and increases operational costs, such as recall expenses. Additionally, the increase in post-cutting waste and defects negatively affects the productivity and efficiency of the business, as such waste requires disposal and correction. Therefore, addressing these issues is critical for the business and requires taking steps to enhance competitiveness and adopt a sustainable production model.

Since the Six Sigma philosophy focuses not only on increasing quality but also on eliminating errors, the Define phase was conducted with the data collected at this point. The problem was defined, and the study moved on to the Measure phase.

3.2. Measure Phase

The Measure phase aims to evaluate the current state of the steel cutting processes with concrete sample data. In this phase, errors occurring during and after the cutting process, chip quantity, and defects were examined through sampling. In this stage of the study, a total of 1000 products in the cutting stage were monitored as a sample for steel cutting processes. Data such as errors during the cutting stage, chip formation after cutting, and defects were collected.

Table 1. Defects & Errors

Number of Products	Defects at Cutting Stage	Chips & Defects after Cutting
1000	25	Average 15

On average, the cutting phase produces 25 defective products out of every 1000. Following the cutting phase, an average of 15 chips and defects are found in each product. The Six Sigma conversion table reveals that, when calculated at a rate of 40 per 1000 products (%96, DPMO: 40,000)), the sigma level of the process comes out to around 3.2 sigma. Defective products entail additional expenses and necessitate processes like quality control, destruction, or remanufacturing. Since this leads to higher costs and lower efficiency in production, the data indicates that the current processes are not reaching the desired level of quality.

During the measure phase, statistical data was collected on defects during the cutting phase, as well as chips and defects after cutting, for the purpose of analyzing the current situation. This data aims to provide a deeper understanding of the quality issues and efficiency gaps within steel cutting processes.

3.3. Analysis Phase

The analysis phase is a critical stage in which the extensive statistical data collected during the measurement phase is analyzed in detail and the underlying root causes of the problem are identified. In this stage, a detailed data-driven analysis of the defects in the steel cutting processes and the chips and imperfections generated after cutting was carried out. As part of this phase, a Fishbone Diagram (Ishikawa or cause and effect diagram) was used.

The Fishbone Diagram, also known as the Ishikawa Diagram or cause and effect diagram, is a tool used to solve a problem or analyze a process. It was developed by Japanese quality control expert Kaoru Ishikawa and is used especially in quality control processes (Ohno & Mekonen, 2023). This diagram is used to systematically identify and understand the causes of a problem (Elyoussoufi et al, 2023).

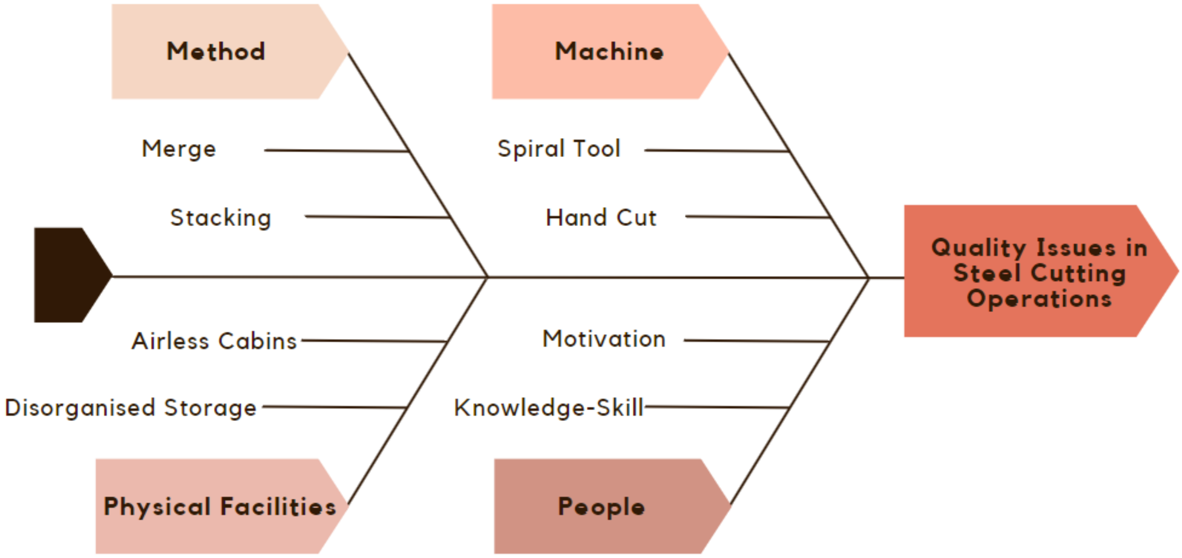

Figure 2. Cause-Effect Diagram (Quality Issues in Steel Cutting Operations)

This fishbone-shaped diagram contains a box placed in the center of the problem. This box represents the problem under investigation. Main headings are identified to understand the causes of the problem. Based on the Cause-Effect Diagram (Figure 2.), the primary causes of substandard products and post-cut chips and defects are linked to factors such as inappropriate cutting parameters, operator errors, and the inadequacy of the chosen spiral tool as a cutting machine.

During this phase of the research, 1000 product defects during the cutting stage and the amount of post-cut chips and defects were statistically analyzed. Following the identification of these issues, a brainstorming session was conducted to explore potential causes and solutions. It was generally inferred that the problems stemmed from specific cutting stage.

Table 3. Cutting Stages with the Biggest Impact on Defective Products

Cutting Stage	Defects	Percentage %
Cutting with Spiral	10	40
Merge	7	28
Stacking	8	32

In addition to defective products, the amount of chips and defects after cutting was also analyzed. Assessing this helps to determine the influence of cutting parameters and machine performance on quality.

Table 4. Amount of chips and defects after cutting

Cutting Parameter	Chip and Defect Amount (gr)	Average Size
Cutting Speed	120	0.5 mm
Blade Angle	90	0.3 mm
Feed Rate	80	0.4 mm

According to Table 4, there was an increase in the amount of chips and defects with increasing cutting speed. Similarly, an increase in blade angle also affected the amount of chips and defects. However, it was observed that the increase in feed rate caused a decrease in the average size. This statistical analysis shows that errors during the cutting stages and chips and defects after cutting can vary depending on certain parameters. This information is important in order to better understand the problems and to find the right solutions. The data obtained at this stage of the study provides a basis for identifying problem areas and formulating improvement strategies. Further interventions will need to focus on the Spiral Cutting stage in particular.

3.4. Improvement Phase

The improvement phase aims to improve the process based on the root causes identified in the analysis phase. At this stage, it is aimed to solve the problem and improve the process by implementing the proposed solutions.

In this phase of the study, recommendations were developed to solve the problems identified in the analysis phase. The data and analysis showed that the biggest effects of the errors during the cutting phase and the chips and defects that occur after cutting are in the cutting parameter caused by the machine and operator.

In this context, it was proposed to build industry 4.0 compatible robotic arms capable of smart cutting. These robot arms can make a more precise and repeatable cut by minimizing human errors during the cutting phase. It can also reduce chips and defects by enabling more precise adjustment of cutting parameters. By minimizing operator errors, this proposal can improve quality and increase the efficiency of the process. It can also make the production process more intelligent and automated, in line with industry 4.0 technologies:

Improvement Strategies

- Integration of Industry 4.0 Compatible Robot Arms:

  - Why: Initial data shows that problems are often caused by method and machine parameters. The integration of technologies such as intelligent manufacturing systems, robot arms, and robotic arms that incorporate Industry 4.0 principles can automate production processes and provide more precise control.
  - How: It was determined that problems were concentrated in the Spiral Cutting stage. At this point, industry 4.0-compliant robot arms can adjust cutting parameters more precisely and minimize operator errors. This can reduce defective product rates.

- Use of Smart Cutting Technology:

  - Cause: Post-cut chips and defects were observed to be associated with certain cutting parameters. Smart cutting technologies can optimize quality by dynamically adjusting parameters such as cutting speed and blade angle.
  - How: The use of Industry 4.0-compliant cutting machines can speed up the feedback loop. Sensors and AI algorithms can reduce post-cut chips and defects, improving the quality of products.

- Operator Training and Awareness:

  - Cause: Operator errors were found to have a significant impact. Training and awareness of operators can help minimize errors.
  - How: Training programs and ongoing information sessions can be organized to ensure that operators are using the correct parameters and optimizing machine performance, especially in the Spiral Cutting stage.

- Data Analytics and Continuous Improvement:

  - Why: Continuous improvement is based on data analytics. The data obtained must be continuously monitored and processed, then processes adjusted accordingly.
  - How: A data analytics platform integrated with Industry 4.0 technologies can monitor processes, identify problem areas and develop recommendations. This triggers a continuous improvement process.

Cost and Benefit Analysis of Improvement Strategies

Improvements to production processes often come with a certain cost. However, these costs can be offset by long-term benefits and competitive advantages. At this stage, we focused on cost and benefit analysis to evaluate the integration of industry 4.0 compliant robot arms, the use of smart cutting technology, operator training and awareness, data analytics and continuous improvement strategies.

Table 4. Robot Arms Cost (TL=Turkish Liras)

Price	948.000 TL
Installation & Labor	160.000 TL
Annual Maintenance Cost (40.000 x 12)	480.000 TL
Total Cost	1.588.000 TL

Improvement Cost was made in the amount of TL 1.588.000 TL. Accordingly, information about the gain or loss of the enterprise in a year or when the improvement will provide gain is given in the table of gains below.

Table 5. Gains Table

Earnings	Amount
Production Capacity Increase	47%
Number of Quality Control Team	3 (15 workers before the improvement)

Total Labor Cost Before Improvement (Annual)	2.700.000 TL
Current Total Labor Cost (Annual)	45.000 TL × 12 = 540.000 TL
Total Savings (Annual)	2.160.000 TL
Return on Improvement (Total Savings - Cost of Improvement)	572.000 TL

Since the reduction in the total number of employees and labor expenses in the enterprise, a significant cost advantage has been attained. Simultaneously, the investment cost of the robot arm was recovered in less than a year. Furthermore, the implementation has greatly benefited the business by supporting capacity improvement.

The analysis indicates that method and machine parameters cause most of the primary issues in the production processes. In this context, integration of Industry 4.0 compatible technologies is a prominent solution. Firstly, the utilization of Industry 4.0 compatible robot arms is considered to minimize errors in the Spiral Cutting stage. These robotic arms can adjust cutting parameters precisely, minimize operator errors, and thus reduce defective product rates.

Additionally, Industry 4.0-compliant cutting technologies can be integrated to minimize post-cut chips and defects. These technologies are capable of enhancing quality by adjusting parameters, such as cutting speed and blade angle, dynamically. Operator training and awareness play an important role in the integration of industry 4.0. Scheduled training will be performed to enable operators to use the right parameters and optimize machine performance. Data analytics will be utilized, along with continuous improvement strategies, to ensure that enhancements are constantly monitored and evaluated. The overall cost and benefits of these methods will be weighed against long-term competitive advantages and gains in operating efficiency.

3.5. Control Phase

Following the implementation of the robotic arm and subsequent process improvements, a careful control phase was initiated to ensure the sustained effectiveness of the improvements. The goal of this phase was to continuously monitor results, take corrective action as needed, and ensure the long-term success of the improvements.

The integration of the robotic arm resulted in a remarkable 47% increase in production capacity, significantly improving the company's operational efficiency. In addition, reducing the number of quality control teams from 15 to 3 resulted in significant labor cost savings without compromising quality standards.

In addition, extensive post-improvement assessments were conducted to evaluate the impact of the improvements. Previously, 40 out of every 1000 units produced were defective. After the improvements, a study of 10,000 units found only four defects, primarily due to raw material or storage issues. The study reduced defects by approximately 90%, significantly improving product quality and operational efficiency. This dramatic reduction in defects contributed to an increase in the sigma level from 3.2 to approximately 4.9, representing a significant improvement in process quality.

The optimization efforts also led to organizational changes. Initially, there were 15 people in the quality control team, but this number was reduced to three after the improvements. As a result, 12 employees were reassigned, three left the company, and nine were transferred to the packaging department. These changes were necessary to align the workforce with the increased production capacity and ensure optimal resource utilization.

In addition, continuous monitoring and control of digital transformation initiatives require hiring a control engineer. This role was critical in overseeing the implementation of digital technologies and ensuring their seamless integration into existing processes.

The control phase of the improvement initiative highlights the importance of continuous monitoring and evaluation to ensure the long-term success of the implemented solutions. By leveraging data-driven insights and organizational adjustments, the company can effectively reap the benefits of process improvements while maintaining its competitive edge in the marketplace.

4. Discussion and Conclusion

This study is focused on a case study of a company in the medical industry regarding their Six Sigma implementation, explicitly dealing with steel-cutting processes. With the critical objectives of reducing errors and waste, improving industry standards, and increasing productivity in steel-cutting processes, this study examines the effectiveness of the Six Sigma methodology in the medical industry.

In the analysis phase, a detailed review of the current state of the process was conducted. This review was used to identify the leading causes of errors and defects in the cutting stages and parameters. The findings clarified the critical points in the process and the potential for improvement. Integrating intelligent robotic arms was proposed in line with industry 4.0 principles in the improvement phase. This proposal led to a significant increase in production capacity and also contributed to cost reduction.

Considering the results of the improvements made, there has been a noticeable increase in the quality level of the company's production processes. For example, whereas before, about 40 out of every 1,000 products had defects after the improvements, this figure was only 4 out of 10,000. This means that the sigma level increased from about 3.2 to 4.9.

The effects of the improvements on the workforce were also taken into account. With the reduction of the number of people in the quality control team, some arrangements were made for the workers. After the improvement process, the number of employees in the quality control team was reduced from 15 to 3. Nine of the remaining 12 employees were assigned to the packaging department with increased production capacity, preventing labor loss. In addition, one control engineer was hired to control the improvement process and monitor the digital transformation. These changes resulted in a significant reduction in operational costs and increased the competitiveness of the business. The placement of workers in new positions increased the efficiency of the enterprise and allowed it to adopt a sustainable production model.

In conclusion, this study shows that the Six Sigma methodology can be successfully applied in the medical industry, and significant results can be achieved in various areas of improvement. Adopting Industry 4.0 principles and using intelligent technologies provide a significant opportunity for businesses to improve their efficiency and gain a competitive advantage. This study guides industry professionals and researchers on operational excellence and quality improvement.

Contributions of the Researchers:

The author contributed as an observer and an external perspective to the improvement of processes.

Acknowledgment:

I express my gratitude to all researchers who contributed to the completion of this research. Your joint efforts and contributions have enhanced the quality of this study and provided a more comprehensive perspective.

Conflict of Interest:

As the author of this article, I would like to state that I have no conflict of interest with any institution or individual. The research represents a neutral and transparent approach.

References

ALobaidi, S. D. J., & ALghabban, T. S. M. K. (2022). The Effect Of Applying The Six-Sigma Approach On The Costs Of Activities Of The General Company For Textile And Leather Industries. Journal of Positive School Psychology, 3971-3990. mail.journalppw.com/index.php/jpsp/article/view/6961

Alzoubi, H. M., In'airat, M., & Ahmed, G. (2022). Investigating the impact of total quality management practices and Six Sigma processes to enhance the quality and reduce the cost of quality: the case of Dubai. International Journal of Business Excellence, 27(1), 94-109. https://doi.org/10.1504/IJBEX.2022.123036

Antony, J., Palsuk, P., Gupta, S., Mishra, D., & Barach, P. (2018). Six Sigma in healthcare: a systematic review of the literature. International Journal of Quality & Reliability Management, 35(5), 1075-1092. https://doi.org/10.1108/IJQRM-02-2017-0027

Arnheiter, M. & J. Maleyeff (2005). The Integration of Lean Management and Six Sigma, The TQM Magazine, 17 (1), 5-18. https://doi.org/10.1108/09544780510573020

Binder, R.V. (1997). Can a Manufacturing Quality Model Work For Software?, IEEE Software, 14(5),101-102, 105. https://ieeexplore.ieee.org/document/605937

Chowdhury, S., Mok, D., & Leenen, L. (2021). Transformation of health care and the new model of care in Saudi Arabia: Kingdom's Vision 2030. Journal of Medicine and Life, 14(3), 347. doi: 10.25122/jml-2021-0070.

Daniyan, I., Adeodu, A., Mpofu, K., Maladzhi, R., & Katumba, M. G. K. K. (2022). Application of lean Six Sigma methodology using DMAIC approach for the improvement of bogie assembly process in the railcar industry. Heliyon, 8(3). 1-14. https://doi.org/10.1016/j.heliyon.2022.e09043

El-Haik, B., & Mekki, K. S. (2011). *Medical device design for six sigma: A road map for safety and effectiveness*. John Wiley & Sons.

Elyoussoufi, S., Mazouzi, M., Cherrafi, A., & Tamasna, E. M. (2022, March). TRIZ-ISHIKAWA diagram, a new tool for detecting influencing factors: a case study in HVAC business. In Proceedings of the International Conference on Industrial Engineering and Operations Management, Istanbul, Turkey.

Escobar, C. A., Macias, D., McGovern, M., Hernandez-de-Menendez, M., & Morales-Menendez, R. (2022). Quality 4.0–an evolution of Six Sigma DMAIC. International Journal of Lean Six Sigma, 13(6), 1200-1238. https://doi.org/10.1108/IJLSS-05-2021-0091

Farahani, B., Firouzi, F., Chang, V., Badaroglu, M., Constant, N., & Mankodiya, K. (2018). Towards fog-driven IoT eHealth: Promises and challenges of IoT in medicine and healthcare. Future generation computer systems, 78, 659-676. https://doi.org/10.1016/j.future.2017.04.036

Harry, M. J. & Stewart, R. (1988). Six Sigma Mechanical Design Tolerancing, 2nd Edition: Motorola University Press, Schaumberg Illinois, US.

Hoeft, T. J., Fortney, J. C., Patel, V., & Unützer, J. (2018). Task‐sharing approaches to improve mental health care in rural and other low‐resource settings: a systematic review. *The Journal of rural health*, 34(1), 48-62. https://onlinelibrary.wiley.com/doi/10.1111/jrh.12229

Hrgarek, N., & Bowers, K. A. (2009). Integrating six sigma into a quality management system in the medical device industry. *Journal of Information and Organizational Sciences*, *33*(1), 1-12. https://hrcak.srce.hr/38710

Kolluri, S., Lin, J., Liu, R., Zhang, Y., & Zhang, W. (2022). Machine learning and artificial intelligence in pharmaceutical research and development: a review. The AAPS Journal, 24, 1-10. https://link.springer.com/article/10.1208/s12248-021-00644-3

Kwak, Y.H. & Anbari F.T. (2006). Benefits, Obstacles and Future of Six Sigma Approach, Technovation. 26 (5-6, 708-715. https://doi.org/10.1016/j.technovation.2004.10.003

Maci, J., & Marešová, P. (2022). Critical factors and economic methods for regulatory impact assessment in the medical device industry. *Risk Management and Healthcare Policy*, 71-91. https://www.tandfonline.com/doi/full/10.2147/RMHP.S346928#d1e131

Marwaha, P. (2022). Lean, Six Sigma and change management: a process improvement approach (Doctoral dissertation, Technische Hochschule Ingolstadt). https://opus4.kobv.de/opus4-haw/files/3534/I001252944Thesis.pdf

McDermott, O., Antony, J., Bhat, S., Jayaraman, R., Rosa, A., Marolla, G., & Parida, R. (2022, a). Lean six sigma in healthcare: A systematic literature review on challenges, organisational readiness and critical success factors. *Processes*, 10(10), 1945. https://doi.org/10.3390/pr10101910

McDermott, O., Antony, J., Sony, M., & Healy, T. (2022, b). Critical failure factors for continuous improvement methodologies in the Irish MedTech industry. *The TQM Journal*, 34(7), 18-38. https://doi.org/10.1108/TQM-10-2021-0289

McHugh, A., & Farrell, F. (2022). Sustaining the Effectiveness of Lean Six Sigma Implementation in a Medical Device Company. In *European Lean Educator Conference* (pp. 165-183). Cham: Springer International Publishing.

McLemore, E. C., Lee, L., Hedrick, T. L., Rashidi, L., Askenasy, E. P., Popowich, D., & Sylla, P. (2022). Same day discharge following elective, minimally invasive, colorectal surgery: A review of enhanced recovery protocols and early outcomes by the SAGES Colorectal Surgical Committee with recommendations regarding patient selection, remote monitoring, and successful implementation. Surgical Endoscopy, 36(11), 7898-7914. https://link.springer.com/article/10.1007/s00464-022-09606-y

Murumkar, A., Teli, S. N., Jadhav, S., Dharmadhikari, S., & Nikam, M. (2018). Integrated Approach of Cost of Quality and Six Sigma. Proceedings. Global Meet on Advances in Design, Materials & Thermal Engineering, Saraswati College of Engineering, Kharghar, Navi Mumbai ذ., 1-6. https://www.researchgate.net/profile/Manoj-Nikam/publication/374631255_Integrated_Approach_of_Cost_of_Quality_and_SixSigma/links/6527b9dd3fa934104b19add0/Integrated-Approach-of-Cost-of-Quality-and-SixSigma.pdf

Noronha, A., Bhat, S., Gijo, E. V., Antony, J., Laureani, A., & Laux, C. (2023). Performance and service quality enhancement in a healthcare setting through lean six sigma strategy. International Journal of Quality & Reliability Management, 40(2), 365-390. https://doi.org/10.1108/IJQRM-07-2021-0226

Obeta, M. U., Maduka, K. M., Ofor, I. B., & Ofojekwu, N. M. (2019). Improving quality and cost diminution in modern healthcare delivery: the role of the medical laboratory scientists in Nigeria. International Journal of Business and Management Invention (IJBMI), 8(03), 08-19. https://www.ijbmi.org/papers/Vol(8)3/Series-1/B0803010819.pdf

Ohno, I., & Mekonen, G. T. (2023). National Movements for Quality and Productivity Improvement with Local Adaptation: The Experience of Japan and Singapore. In Introducing Foreign Models for Development: Japanese Experience and Cooperation in the Age of New Technology (pp. 105-136). https://link.springer.com/chapter/10.1007/978-981-99-4238-1_4

O'Connor, P. D. and A. Kleyner (2012). Practical Reliability Engineering (5th Edition). Chichester, West Sussex, John Wiley & Sons, Ltd, UK.

Parab, A., Teli, S. N., & Jagtap, M. M. (2016). Statistical Process Control and Six Sigma an Integrated approach to Improve Process in Medical Device Industry. *Int. J. of Res. in Aero. and Mech. Engg*, 4(5), 85-97. https://www.researchgate.net/publication/317348409

Pyzdek, T. (2003). The Six Sigma Handbook: A Complete Guide For Green Belts, Black Belts, And Managers At All Levels, McGraw-Hill, New York, US.

Rathi, R., Vakharia, A., & Shadab, M. (2022). Lean six sigma in the healthcare sector: A systematic literature review. *Materials Today: Proceedings*, *50*, 773-781. https://doi.org/10.1016/j.matpr.2021.05.534

Salditt, P., & Bothell, W. A. (2004). Trends in medical device design and manufacturing. *SMTA News and Journal of Surface Mount Technology*, *17*, 19-24. https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=9862c557699dd498cd41215136cc47b2fc9fdaba

Sim, C. L., Jusoh, M. S., & Akmar Ishak, N. (2019). Investigating the influence of lean six sigma practices on quality performance in medical device manufacturing industry. *Voice of Academia (VOA)*, 15(1), 120-130. https://voa.uitm.edu.my/

Sim, C. L., Li, Z., Chuah, F., Lim, Y. J., & Sin, K. Y. (2022). An empirical investigation of the role of lean six sigma practices on quality performance in medical device manufacturing industry. *International Journal of Lean Six Sigma*, *13*(3), 671-691. https://doi.org/10.1108/IJLSS-06-2020-0089

Singh, M. & Rathi, R. (2024), "Implementation of environmental lean six sigma framework in an Indian medical equipment manufacturing unit: a case study", The TQM Journal, Vol. 36 No. 1, pp. 310-339. https://doi.org/10.1108/TQM-05-2022-0159

Singh, M., Rathi, R., Antony, J., & Garza-Reyes, J. A. (2023). A toolset for complex decision-making in analyze phase of Lean Six Sigma project: a case validation. International Journal of Lean Six Sigma, 14(1), 139-157.

Sharma, A., Bhanot, N., Gupta, A., & Trehan, R. (2022). Application of Lean Six Sigma framework for improving manufacturing efficiency: a case study in Indian context. International Journal of Productivity and Performance Management, 71(5), 1561-1589. https://doi.org/10.1108/IJPPM-05-2020-0223

Sodhi, H. (2020). When industry 4.0 meets lean six sigma: a review. *Industrial Engineering Journal*, *13*(1), 1-12. https://www.researchgate.net/publication/338752017

Sordan, J.E., Marinho, C.A., Oprime, P.C., Pimenta, M.L. and Andersson, R. (2023), "Characterization of Lean Six Sigma projects in healthcare settings: empirical research", Benchmarking: An International Journal, Vol. 30 No. 10, pp. 4058-4075. https://doi.org/10.1108/BIJ-03-2022-0183

Sodhi, H. S. (2023). An investigation towards identifying and analysing the failure factors for the implementation of scrap reduction techniques in Indian SMEs. International Journal of Process Management and Benchmarking, 14(2), 139-154. https://doi.org/10.1504/IJPMB.2023.130961

Thakur, V., Akerele, O. A., & Randell, E. (2023). Lean and Six Sigma as continuous quality improvement frameworks in the clinical diagnostic laboratory. Critical Reviews in Clinical Laboratory Sciences, 60(1), 63-81. https://doi.org/10.1080/10408363.2022.2106544

Tsung, F., & Wang, K. (2023). Six Sigma. In Springer handbook of engineering statistics (pp. 239-259). London: Springer London.

Vadori, R. (2020). Quality control and standards in manufacturing of medical devices. In Metallic Biomaterials Processing and Medical Device Manufacturing (pp. 549-568). Woodhead Publishing.

Yusof, N., & Lee, K. L. (2022). Improve Product Quality and Production Process with Integration of Six Sigma and Quality Management System ISO 9001: A Case Study of Bakery Shop in France. International Journal of Industrial Management, 14(1), 557-579. https://journal.ump.edu.my/ijim/article/view/7598