

The Importance of Total Quality Management Practices on Quality Performance in the Medical Device Manufacturing Industry: A Literature-Based Review

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ABSTRACT

This study is to conduct a literature research on in the role of Total Quality Management (TQM) practices in increasing the quality performance of medical devices within the medical device manufacturing industry. Medical devices range from simple instruments like gloves to complex devices like pacemakers and MRI machines, have a direct impact on patient health and safety, making quality management a critical aspect of their production. The study adopts research, combining past research on manufacturers and commentary from industry experts. Key TQM practices identified include customer focus, employee involvement, process management, supplier quality management, continuous improvement, employee training and development. According to research reveal that there are significant positive relationships between TQM practices and quality performance indicators such as defect reduction, regulatory compliance, customer satisfaction and operational efficiency. To further improve quality performance in the medical device industry, the long-term impact of Total Quality Management practices should be investigated.

Keywords: Total Quality Management, Medical Device Manufacturing, Regulatory Compliance.

Tıbbi Cihaz Üretim Endüstrisinde Kalite Performansında Toplam Kalite Yönetimi Uygulamalarının Önemi: Literatür Tabanlı Bir İnceleme

ÖZET

Bu çalışma, tıbbi cihaz üretim endüstrisinde Toplam Kalite Yönetimi (TKY) uygulamalarının tıbbi cihazların kalite performansını artırmadaki rolü üzerine bir literatür araştırması yapmaktır. Eldiven gibi basit aletlerden kalp pili ve MRI makineleri gibi karmaşık cihazlara kadar uzanan tıbbi cihazlar, hasta sağlığı ve güvenliği üzerinde doğrudan bir etkiye sahiptir ve bu da kalite yönetimini üretimlerinin kritik bir yönü haline getirmektedir. Çalışma, üreticiler üzerinde yapılan geçmiş araştırmaları ve sektör uzmanlarının yorumlarını bir araya getiren bir araştırmayı benimsemektedir. Belirlenen temel TKY uygulamaları arasında müşteri odaklılık, çalışan katılımı, süreç yönetimi, tedarikçi kalite yönetimi, sürekli iyileştirme, çalışan eğitimi ve gelişimi yer almaktadır. Araştırmaya göre TKY uygulamaları ile hataların azaltılması, mevzuata uyum, müşteri memnuniyeti ve operasyonel verimlilik gibi kalite performans göstergeleri arasında önemli pozitif ilişkiler bulunmaktadır. Tıbbi cihaz sektöründe kalite performansını daha da iyileştirmek için Toplam Kalite Yönetimi uygulamalarının uzun vadeli etkisi araştırılmalıdır.

Anahtar Kelimeler: Toplam Kalite Yönetimi, Tıbbi Cihaz Üretimi, Hukuki Uygunluk.

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1. INTRODUCTION

This research aims to investigate how implementing Total Quality Management (TQM) practices can improve the quality performance of devices, in the medical device manufacturing sector.

The medical device manufacturing industry plays a role in healthcare by providing equipment for diagnosis, treatment and patient care. These devices range from tools to electronic device and their safety and effectiveness are vital for patient wellbeing. Ensuring that these devices meet high quality standards is essential due to their impact on health and the potential risks associated with substandard manufacturing (Abbas, 2020).

In today's regulated medical device manufacturing field maintaining highest quality performance is importance. Given the nature of devices in safeguarding patient health and safety a rigorous approach to quality management is essential. Total Quality Management has emerged as a framework in this industry driving enhancements and fostering a culture of excellence. This article delves into how TQM practices contribute to improving the quality performance of devices by examining the specific methods and strategies adopted by industry leaders to meet strict regulatory standards and exceed customer expectations.

Total Quality Management represents an integrated management approach focused on enhancing product and process quality, throughout an organization continuously. Total Quality Management brings together all areas of a company (such, as marketing, finance, design, purchasing, engineering and production) to focus on fulfilling customer needs and organizational goals. In the field of medical device manufacturing applying TQM principles can lead to enhancements in product quality, adherence to regulations, operational efficiency and overall customer satisfaction. This ensures that the devices produced are safe, efficient and dependable.

TQM is a management strategy that emphasizes long term success through meeting customer needs by involving all members of an organization in enhancing processes, products and services. It involves an approach to achieving quality in all aspects of operations by putting emphasis on customer satisfaction, improvement and engaging all employees. By ingraining quality into the culture TQM aims to minimize errors decrease variability and improve performance. In industries like medical device manufacturing where precision and reliability are factors for success TQM plays a role in ensuring that products meet strict safety standards adhere to regulatory requirements and meet customer expectations. The comprehensive nature of TQM helps organizations establish resilient quality systems that can adapt to advancements in technology and changing market demands while safeguarding public health.

However the implementation of TQM, in the medical device manufacturing sector comes with its set of challenges.

In today's business world, medical device companies face a maze of rules and regulations, like ISO 13485, GMP and FDA guidelines that require record keeping and adherence. The evolving technology landscape and the growing complexity of equipment make it even harder to maintain consistent quality standards. Despite these obstacles many businesses have used Total Quality Management (TQM) to make strides in enhancing quality performance setting new standards for the sector.

This piece will explore real life examples of medical device makers successfully embracing TQM practices showcasing the benefits seen in product quality, operational efficiency and customer satisfaction. It will also delve into factors for TQM adoption such as strong leadership support engaged employees and ongoing improvement efforts. By grasping the role TQM plays in medical device manufacturing stakeholders can better understand its importance in ensuring effective products – ultimately leading to better patient outcomes and healthcare quality worldwide (Olga et al, 2020).

With the recognized benefits of TQM the medical device industry faces hurdles when putting it into practice. These challenges include regulations, product designs requiring precision and reliability as well as navigating global competition pressures for innovation, amidst cost concerns. Medical device regulations are constantly updated as a solution to encountered problems or as a precaution against identified risks. Medical device manufacturers and providers are expected to keep up with these changes. The effort to keep up with rapid change is one of the problems encountered in this sector (Huusko et al, 2023).

Dealing with these obstacles by implementing Total Quality Management (TQM) techniques is vital to improve the quality of devices ensuring they meet strict safety and effectiveness criteria (Oakland, 2014).

To sum up in the changing landscape of the medical device sector embracing TQM practices remains crucial for companies looking to stay competitive while upholding highest quality standards. This article seeks to give a look, at how TQM influences the quality performance of devices providing valuable insights for professionals, in the industry regulatory agencies and academic circles (Oakland, 2014).

2. THE CONCEPT OF TOTAL QUALITY MANAGEMENT (TQM)

Total Quality Management (TQM) is an approach, to managing operations with a focus on enhancing product and process quality in organizations . In the field of medical device manufacturing implementing TQM is crucial as it directly influences health and safety through ensuring the quality of devices. This review explores aspects of TQM and its

impact on the quality performance of devices covering foundational theories, key practices, challenges in implementation specific to the medical device industry historical perspectives on quality management systems for medical devices and their effects on quality performance (Kannan et al, 2005).

The history of quality management within the medical device sector is closely tied to the development of frameworks designed to safeguard well being and product effectiveness. Instances of device failures and recalls that posed risks to patients underscored the necessity for Quality Management Systems (QMS) in medical device production. The growing complexity and diversity of devices in the mid 20th century led to an increase in incidents involving events related to these devices. In response the United States introduced the Medical Device Amendments of 1976 as part of the Food, Drug and Cosmetic Act. This legislation mandated manufacturers compliance with Good Manufacturing Practices (GMPs). Established guidelines, for medical devices (Goh et al, 2010).

One of the incidents that highlighted the importance of strict quality controls was the thalidomide tragedy that occurred in the late 1950s and early 1960s. Thalidomide, a medication promoted as a sedative resulted in birth defects, in thousands of newborns. While it was primarily a catastrophe it shed light on the devastating outcomes of testing and quality control practices influencing regulatory measures for medical devices. In the 1970s issues with the Dalkon Shield device (IUD) led to injuries and fatalities due to design flaws and manufacturing errors. This event further underscored the need for regulatory supervision and quality assurance procedures in the development, production and post market monitoring of medical devices (Hoerl and Knee, 2012).

W. Edwards Demings 14 Points for Management serve as the foundation of Total Quality Management (TQM). Deming stressed the importance of establishing a purpose embracing a quality philosophy reducing reliance on inspection processes and fostering an environment of continuous enhancement. His principles advocate for leadership dedication and holistic thinking as aspects of quality management. Demings contributions his focus on the Plan Do Check Act (PDCA) cycle have had an impact, on contemporary quality management methodologies (Deming, 1986).

Joseph Juran introduced the concept known as Quality Trilogy which involves quality planning, quality control and quality enhancement initiatives. Jurans trilogy emphasizes the role of management, in driving quality initiatives and the necessity of collaborative teams from various departments to tackle quality challenges. Juran advocates for a quality approach that prioritizes preventing issues over identifying and fixing them which has significantly influenced quality management strategies (Juran, 1988).

Philip Crosby's belief in "Zero Defects" and his focus, on the cost of quality (CoQ) argue that it is more cost efficient to prevent defects than correct them. Crosby's work highlights the advantages of quality management. Stresses the importance of maintaining high standards. His idea that "quality is free" suggests that the expenses linked to quality far exceed the investments needed to attain quality (Crosby, 1979).

The rise, in complexity and potential risks linked to devices prompted the establishment of standards and regulations. In 1987 ISO rolled out ISO 9001 a quality management standard applicable across all sectors. This was succeeded by ISO 13485 in 1996 specifically catering to the quality management needs of medical device makers. ISO 13485 has emerged as the benchmark for Quality Management Systems (QMS) in the medical device domain outlining criteria for processes ranging from design and development to production, installation and maintenance. It underscores risk management, adherence to regulations and consistent production of efficacious devices (Kaynak, 2003).

Total Quality Management (TQM) is anchored on principles like customer focus, continuous enhancement, process centricity and active employee participation. These tenets collectively foster the attainment of top notch standards and operational supremacy.

3. TOTAL QUALITY MANAGEMENT PRINCIPLES IN MEDICAL DEVICES SECTORS

The global healthcare device market is predicted to reach \$603.5 billion by 2023 with a growth rate of 5.4% (according to MarketsandMarkets, 2018). The United States boasts the world's medical device market, valued at about \$156 billion, in 2017 and set to hit \$208 billion by 2023 (as per SelectUSA, 2018). In Europe the medical device sector was valued at €120 billion in 2020 with Germany, France and the United Kingdom standing out as markets (citing MedTech Europe, 2021). Although the global medical device market has a high volume, in the field of medical device manufacturing industry in particular poses hurdles when it comes to implementing and upholding Total Quality Management practices due, to demands and technological intricacies, alongside the essential aspect of ensuring uniform quality standards throughout different production phases.

Here's how total quality management principles can be used in medical devices:

- a. Continuous Improvement; Implementing a Quality Management System (QMS) promotes a culture of progress by urging organizations to evaluate and enhance their operations and products. Strategies, like Six Sigma, Lean principles and Total Quality Management (TQM) play roles within a QMS framework by aiding in reduction, efficiency improvement and elevated customer satisfaction levels. Continuous advancement remains essential in an industry marked by innovations and evolving patient requirements. Numerous trends are influencing the landscape of the medical device industry. These trends encompass the rising demand for procedures increased

prevalence of chronic illnesses and greater acceptance of wearable medical devices. Moreover the COVID 19 pandemic has hastened the adoption of telemedicine and remote monitoring tools underscoring the significance of connectivity and digital health solutions. Data underscores both advancements in technology well as economic importance, within the medical device domain (Sadikoglu ve Olcay, 2014).

- b. **Customer Orientation;** Quality management practices that focus on meeting customer needs and expectations through activities, like quality control measures and feedback systems play a role in maintaining the trust and loyalty of customers in the medical device sector. Academic research has demonstrated a connection between quality management practices and customer satisfaction, within the field of healthcare technology. (Shaibun, 2021) Ensuring standards during the design stage is crucial, for meeting customer needs and complying with regulations. This not boosts customer happiness but lowers the chances of product recalls. (Hudson, 1991).
- c. **Supplier Management** Managing suppliers is vital, in the field of manufacturing medical device to uphold quality control standards successfully and efficiently impact the excellence and dependability of end products in a regulated sector such, as medical devices. Improving supplier quality also known as supplier quality development plays a role, in reducing expenses linked to goods and services within the medical device manufacturing sector by focusing efforts strategically to boost the quality and efficiency of suppliers. (Noshad, 2015) The medical device sector frequently refrains from subcontracting because of worries regarding upholding the integrity of product standards. Establishing collaborations guarantees that both quality and delivery demands are fulfilled successfully while also managing obligations effectively. (Magdy, 2023).
- d. **Process Management;** Government agencies like the U.S. Food and Drug Administration (FDA) the European Medicines Agency (EMA) and other international bodies enforce guidelines concerning the development, production and post market monitoring of devices. A Quality Management System (QMS) assists manufacturers in adhering to these regulations by offering a framework to ensure product quality and uniformity. ISO 13485, a standard tailored to devices establishes the criteria for a QMS and is widely embraced within the sector (ISO, 2016). A QMS integrates risk management procedures to identify, assess and mitigate risks throughout the product lifecycle. This proactive strategy aids in averting failures and guarantees resolution of any issues to safeguard patient well being (Nair, 2006). Establishing a quality control system following the guidelines set by ISO 13485 and the European Union Medical Device Regulation (EU MDR 2017 / 745) is crucial, for ensuring product safety and meeting standards. The implementation of these regulations necessitates a risk focused strategy to recognize risks effectively and take measures to address them appropriately. (Sharma, 2023)

- e. Leadership and employee engagement As per ISO 13485:2016—a framework for QMS in the medical device sector— TQM integration necessitates meticulous documentation, record control and systematic managerial evaluations. While ongoing enhancement stands as an element of QMS success story; keeping this drive alive can pose challenges. Sustaining it demands vigilance over processes, data gathering and analysis efforts, alongside implementation of enhancements. Organizations may encounter difficulties, in maintaining an lively improvement process for all staff members (Antony et al. 2017). Continuous improvement is encouraged by TQM through conducting audits and fostering communication, between departments. Teamwork plays a role, in identifying and tackling quality issues.(Yeh, T., et al.,2015).

Manufacturers face challenges when it comes to implementing quality management. One major hurdle is dealing with the strict environment. Meeting regulations, in countries and regions can be demanding in terms of time and resources. Keeping up with evolving regulations only adds to the complexity (Schuh et al., 2015). Setting up a QMS requires investments in time, money and manpower. Small manufacturers especially may find it hard to allocate resources, for establishing and maintaining a QMS. This includes expenses related to training staff investing in quality management tools and carrying out audits and inspections (Terziovski et al., 2003). Maintaining the standards and upkeep of equipment requires checks and the implementation of a well rounded quality control system that can anticipate issues and ensure consistent quality at every stage of production. (Li, 2022). Implementing and upholding Total Quality Management presents not hurdles but also requires navigating through human and political barriers, within the company such as securing support, from all parties involved and addressing any resistance to change. (Martins, 2015).

4. CONCLUSION

Quality management practices play a role, in the field of manufacturing for medical devices by guaranteeing top notch quality and the safety and efficacy of products. This approach not boosts efficiency and customer contentment but also maintains compliance with regulations and fosters ongoing enhancements. Strong leadership capabilities, sound communication strategies and consistent training form the foundation, for an implementation of quality management practices.

Customer satisfaction is a principle of Total Quality Management (TQM) emphasizing the significance of understanding and fulfilling customer needs and expectations. In the field of devices this means guaranteeing that devices are secure, efficient and dependable. Studies have demonstrated that organizations that prioritize customer satisfaction are more likely to achieve product quality and customer contentment (Zhang et al., 2012).

The commitment of leadership plays a role, in the execution of TQM. Senior management must exhibit a dedication to quality through planning, resource allocation and continuous involvement in quality projects. Research suggests that leadership commitment is closely linked to TQM implementation and enhanced quality performance (Prajogo & Sohal 2006).

Incorporating employees into TQM procedures like quality circles and cross functional teams fosters an environment of enhancement and creativity. Engaging employees, in quality ventures aids in recognizing and resolving issues efficiently resulting in quality results (Wilkinson et al., 1998).

Process management entails defining, overseeing and enhancing processes to boost efficiency and quality. In the medical device sector process management guarantees that manufacturing processes are standardized, managed and consistently enhanced to meet requirements and quality standards (Flynn et al., 1995).

Managing the quality of suppliers involves collaboration, with them to guarantee that the materials and components used in devices meet the required quality standards. Effective supplier management strategies, such as conducting supplier audits and establishing quality agreements play a role in upholding high product quality and meeting standards.

Continuous improvement, which often involves methodologies like Six Sigma and Lean focuses on making improvements in processes, products and services. The adoption of improvement methods has been proven to reduce defects cut costs and enhance overall quality performance within the medical device sector.

The medical device industry is heavily regulated, with requirements set by bodies such as the FDA, EMA and ISO. Balancing compliance with these regulations while implementing Total Quality Management (TQM) practices can be challenging due to the complexity and rigor of these standards.

Implementing TQM practices necessitates investments in terms of time, finances and human resources. Smaller manufacturers may encounter challenges in allocating resources to support TQM initiatives, which can impede their ability to achieve desired quality outcomes.

Ensuring that suppliers uphold quality standards is crucial, for enhancing the quality performance of devices. Managing and coordinating supplier quality can pose challenges in a supply chain, with various suppliers (Robinson & Malhotra 2005).

Studies have consistently demonstrated that implementing TQM practices results in decreases, in product defects. By emphasizing process enhancement, staff training and the management of supplier quality manufacturers can lower defect occurrences. Enhance the dependability of medical devices (Powell, 1995).

TQM practices play a role, in helping manufacturers meet standards effectively. By establishing quality management systems and continuously improving their processes companies can ensure that their products align with guidelines and industry norms. One of the outcomes of implementing TQM is a customer experience. By prioritizing customer needs and consistently enhancing product quality manufacturers can deliver products that not meet but surpass customer expectations leading to increased customer loyalty and satisfaction.

Research emphasizes the significance of TQM practices in elevating the quality performance of devices within the manufacturing sector. Key TQM practices such as focusing on customers demonstrating leadership commitment involving employees managing processes efficiently ensuring supplier quality promoting improvement making data driven decisions and investing in training and development are crucial for achieving high quality results. Despite challenges, like meeting standards, limited resources, resistance to change coordinating with suppliers and managing data during implementation; the documented benefits of TQM include reducing defects ensuring compliance with regulations enhancing customer satisfaction levels and improving operational efficiency.

In the medical device industry having a Quality Management System is crucial to guarantee safety meet regulations manage risks effectively and drive ongoing improvement. However implementing a QMS poses challenges, for manufacturers such as meeting standards, limited resources, internal resistance coordinating with suppliers and handling data efficiently. To overcome these obstacles, strong leadership, proper resource allocation, effective change management tactics and a dedication, to enhancement are necessary. By tackling these hurdles head on manufacturers can ensure the creation of notch devices that not only meet regulatory requirements but also surpass customer expectations.

Statement of Research and Publication Ethics

In all stages of the research and publication process, the principles of research and publication ethics set out by the Journal of Manisa Celal Bayar University Graduate School of Social Sciences were adhered to.

Contribution Rate of Authors to the Article

All authors were responsible for making an equal contribution to the study.

Declaration of Interest

The authors have no financial or personal interests that could be perceived as influencing their work.

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