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Technological Management of Medical Device Companies Supporting Overseas Trade

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Abstract: The global medical device industry has experienced significant growth in recent years, driven by technological innovation and rising demand for healthcare solutions. This paper investigates how effective technological management can enhance the overseas trade performance of medical device companies. By examining industry trends, strategic technology deployment, and representative case studies, the study identifies key enablers for overcoming regulatory barriers, fostering innovation, and sustaining competitiveness in international markets. The findings highlight the pivotal role of integrated technological management in supporting long-term success in global trade.

Keywords: medical devices; technological management; international trade; innovation; global competitiveness

1. Introduction

The global medical device industry has experienced significant growth over the past few decades, driven by advancements in healthcare technologies and an increasing demand for medical solutions that enhance patient outcomes. As healthcare systems worldwide strive to meet the challenges of aging populations, rising healthcare costs, and the need for more effective treatments, the role of medical devices has become more crucial than ever. From diagnostic equipment and surgical instruments to innovative therapeutic devices, the medical device sector is at the forefront of addressing these complex healthcare needs.

In this rapidly evolving market, medical device companies face numerous challenges in maintaining competitiveness, especially in the context of international trade. Expanding into overseas markets presents both opportunities and obstacles, as companies must navigate varying regulatory environments, protect intellectual property, and manage complex global supply chains. This is where effective technological management becomes indispensable. By adopting robust technological strategies, medical device companies can not only optimize their product development processes but also enhance their ability to operate across borders while ensuring compliance with international standards.

This paper aims to explore the critical role of technological management in supporting the overseas trade activities of medical device companies. The following sections will examine the key technological trends shaping the industry, the strategies that companies can employ to overcome international trade barriers, and the best practices for fostering innovation and ensuring regulatory compliance. Through case studies of successful medical device companies, this paper will highlight how strategic technological management can serve as a key enabler for global expansion, offering valuable insights for both industry practitioners and policymakers.

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2. Overview of the Medical Device Industry

The global medical device industry has evolved into a dynamic and competitive sector, with its pivotal role in healthcare becoming increasingly evident. As technological advancements continue to reshape the healthcare landscape, the medical device industry faces growing demand for innovative solutions that improve patient care, increase efficiency, and reduce costs. This chapter aims to provide an overview of the medical device industry, focusing on its market dynamics and key technological trends that are shaping its future [1].

2.1. Market Dynamics

The medical device industry is characterized by rapid growth and increasing globalization. As of recent estimates, the global medical device market is valued at hundreds of billions of dollars and is projected to expand steadily over the coming years [2]. This growth is driven by several key factors, including:

- 1) **Aging Population:** As the global population ages, there is an increasing prevalence of chronic diseases and conditions that require advanced medical devices. This demographic shift has led to higher demand for medical devices, particularly those related to diagnostics, monitoring, and treatment of age-related health issues such as diabetes, cardiovascular diseases, and orthopedic conditions.
- 2) **Technological Advancements:** The integration of digital health technologies, such as telemedicine, wearable health devices, and artificial intelligence (AI), has revolutionized the medical device market. These innovations not only improve the quality of care but also enhance the efficiency of healthcare systems, leading to greater adoption of medical devices worldwide.
- 3) **Regulatory Landscape:** The medical device market is heavily regulated, with each country or region having its own set of regulatory standards. Regulatory bodies, such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other national authorities, play a crucial role in ensuring that medical devices meet safety and efficacy standards. The complexity of these regulations presents challenges for companies seeking to enter international markets, but also provides an opportunity for firms that are able to navigate these requirements effectively [3].
- 4) **Economic Factors:** Economic conditions, such as healthcare expenditure, government policies, and funding for healthcare infrastructure, also significantly impact the medical device industry. In emerging markets, rising income levels and improving healthcare access are expanding the market for medical devices, while developed countries continue to demand higher-quality and more sophisticated products.

2.2. Technological Trends

Technological innovation is at the heart of the medical device industry, driving both market growth and the transformation of healthcare delivery. Several technological trends are currently shaping the industry, including:

- 1) **Internet of Medical Things (IoMT):** The proliferation of connected devices, which can collect and share patient data in real-time, is creating new opportunities for medical professionals to monitor and manage patient conditions more effectively. IoMT devices include wearables such as heart rate monitors, glucose meters, and even connected surgical instruments. These devices allow for continuous patient monitoring, remote diagnostics, and improved decision-making, ultimately enhancing patient care [4].

- 2) **Artificial Intelligence and Machine Learning:** AI and machine learning technologies are being increasingly integrated into medical devices, particularly in diagnostic imaging, predictive analytics, and personalized medicine. AI algorithms are capable of analyzing vast amounts of medical data, such as medical images and genetic information, to assist in diagnosing conditions, predicting patient outcomes, and recommending treatment options. This trend is expected to continue to evolve as AI becomes more capable of improving the accuracy and efficiency of medical devices.
- 3) **3D Printing:** 3D printing has emerged as a transformative technology in the medical device industry. It allows for the rapid prototyping and customization of medical devices, such as prosthetics, implants, and surgical instruments. This technology offers greater flexibility and precision in device manufacturing, making it possible to create personalized medical solutions tailored to individual patients [5].
- 4) **Minimally Invasive and Robotic Surgery:** Advances in minimally invasive surgical techniques, aided by robotic systems, are enhancing the capabilities of surgeons and reducing patient recovery times. Robotic surgery systems, such as the da Vinci Surgical System, allow for more precise, controlled procedures with smaller incisions, leading to fewer complications and faster healing for patients.
- 5) **Regenerative Medicine and Biotechnology:** Emerging fields such as regenerative medicine and biotechnology are influencing the development of medical devices, particularly in the areas of tissue engineering, stem cell therapies, and biologic implants. These innovations aim to repair or replace damaged tissues and organs, offering promising solutions for patients with chronic conditions or injuries that are not amenable to traditional medical interventions [6].

In summary, the medical device industry is undergoing a period of significant transformation driven by both market dynamics and technological advancements. These changes are reshaping the competitive landscape and offering new opportunities for companies to innovate and expand globally [7]. Understanding these market dynamics and technological trends is crucial for medical device companies as they navigate the complexities of the global healthcare market.

3. Understanding Technological Management

Technological management plays a crucial role in enabling companies to innovate, maintain operational efficiency, and comply with industry standards. In this chapter, we explore the definition and theoretical frameworks that underpin technological management, and its strategic importance in the medical device industry [8].

3.1. Definition and Theoretical Framework

Technological management refers to the systematic approach to managing an organization's technological capabilities to align with business objectives. It involves overseeing technology development, implementation, and optimization to gain a competitive edge. In the medical device industry, technological management is vital, as it ensures that companies remain innovative while meeting rigorous regulatory standards [9].

Several key concepts form the theoretical foundation of technological management:

- 1) **Technology Life Cycle (TLC):** This model outlines the stages a technology passes through, from its creation to its eventual decline. By understanding the TLC, medical device companies can make strategic decisions about when to innovate, scale technologies, or phase out outdated ones.
- 2) **Innovation Management:** The process of generating, developing, and implementing new technologies is fundamental in the medical device sector. Effective innovation management allows companies to stay ahead in a highly competitive market.

- 3) **Technology Strategy:** This framework ensures that technological investments align with a company's overall business goals. Technology strategy focuses on which innovations to pursue, managing intellectual property, and ensuring scalability across international markets.

These concepts form the basis for making informed decisions that can enhance both short-term and long-term business success.

3.2. Strategic Relevance in Medical Device Sector

Technological management is of paramount strategic importance in the medical device industry. Given the fast-paced nature of innovation, the complexity of regulatory environments, and the need to stay competitive globally, companies must strategically manage their technological assets to thrive [10]. The following are the key areas where technological management holds strategic significance:

- 1) **Regulatory Compliance:** Medical device companies must navigate complex regulatory frameworks in different markets. Technological management ensures that products meet safety and efficacy standards, which is essential for gaining approval and entering global markets.
- 2) **Innovation and Product Development:** Innovation is central to the medical device sector. Technological management helps streamline research and development (R&D) efforts, ensuring that products are developed on time and meet the growing demands of healthcare providers and patients.
- 3) **Cost Efficiency and Operational Effectiveness:** Managing technology effectively can lead to significant cost savings through automation, supply chain optimization, and process improvements. Companies that embrace technological tools to enhance operational efficiency can improve profitability while maintaining high-quality standards.
- 4) **Global Market Expansion:** As medical device companies expand globally, technological management helps them adapt products to regional healthcare needs, comply with various regulatory standards, and establish strategic partnerships in international markets.

To better understand the strategic role of technological management in these areas, Table 1 below highlights its impact on various strategic dimensions within the medical device sector. This table provides a visual overview of how technological management influences business outcomes across key strategic areas [11,12].

Table 1. Strategic Relevance of Technological Management in the Medical Device Sector.

Strategic Area	Technological Management Role	Impact on Business Outcomes
Regulatory Compliance	Managing certification processes, ensuring compliance with local and international standards.	Reduces risk of non-compliance, facilitating market entry.
Innovation and Product Development	Overseeing R&D processes, ensuring timely innovation cycles.	Accelerates product development, enhances competitiveness.
Cost Efficiency	Implementing automation, data analytics, and process optimization to reduce operational costs.	Increases profitability, enhances operational efficiency.
Global Market Expansion	Leveraging technology to adapt products for international markets, ensuring global coordination.	Enables successful entry into new markets, improving global reach.

The table above summarizes the key roles of technological management in driving business outcomes across strategic areas within the medical device sector. These areas,

including regulatory compliance, product development, cost efficiency, and global expansion, are all influenced by the effective management of technology. The table helps illustrate how technological management enables companies to navigate challenges and seize opportunities in a competitive global marketplace.

4. Overseas Trade Challenges in the Medical Device Industry

The global expansion of medical device companies presents a host of opportunities, but it also introduces significant challenges. Navigating the complexities of overseas trade requires companies to overcome various barriers, from regulatory hurdles to intellectual property (IP) issues, and to address the intricacies of supply chain management. Understanding these challenges and developing strategies to mitigate them is crucial for medical device companies seeking to maintain competitiveness in international markets [13].

4.1. Regulatory Barriers

One of the most formidable challenges in the medical device industry when entering foreign markets is the complex and often restrictive regulatory environment. Different countries and regions have their own sets of regulations governing the safety, efficacy, and marketability of medical devices, making it difficult for companies to ensure compliance across multiple jurisdictions.

In the United States, for instance, the Food and Drug Administration (FDA) has strict guidelines for medical device approval, which involve extensive clinical testing and documentation. Similarly, the European Union requires medical devices to meet the standards set out in the Medical Device Regulation (MDR), which imposes rigorous safety and performance requirements. For companies operating in multiple markets, this means navigating a labyrinth of rules and processes that can vary significantly from one country to another. Failure to comply with these regulations not only leads to delays in market entry but can also result in hefty fines and reputational damage.

In addition, countries such as China and India have been strengthening their regulatory frameworks in recent years, requiring foreign medical device companies to invest time and resources in understanding and complying with local standards. As a result, many companies are now turning to local regulatory experts to guide them through the approval processes and ensure that their products meet both global and regional regulatory standards.

4.2. Intellectual Property Issues

Intellectual property (IP) protection is another critical concern for companies involved in overseas trade of medical devices. The risk of intellectual property theft or unauthorized copying is a pervasive issue in global markets, particularly in regions where IP enforcement is weak or inconsistent.

Medical device companies rely heavily on proprietary technologies, patents, and trade secrets to maintain a competitive edge. However, the protection of these intellectual assets can be challenging when expanding into markets with less robust IP laws or when the enforcement of existing laws is inconsistent. For instance, in some emerging markets, medical device patents may not be as well protected as they are in more developed economies, leading to potential infringement by local competitors. This situation can result in the erosion of a company's competitive advantage, as cheaper, counterfeit versions of their products may flood the market.

Moreover, navigating the patent landscape in multiple countries can be a cumbersome and expensive process. Companies must carefully manage their patent portfolios to avoid infringement issues, as well as ensure that their products do not inadvertently violate existing patents in foreign markets. This complexity makes it essential for medical device companies to employ a proactive IP strategy, including securing patents in key

markets and closely monitoring developments in IP law in the countries where they operate.

4.3. Supply Chain and Logistics

Supply chain and logistics challenges are another significant hurdle for medical device companies operating globally. The medical device supply chain is inherently complex, involving the sourcing of materials, manufacturing, assembly, and distribution across multiple regions. Any disruption in this intricate network can lead to delays, increased costs, and even the inability to meet demand in critical markets.

The COVID-19 pandemic underscored the vulnerability of global supply chains, with disruptions affecting the availability of raw materials, shipping delays, and labor shortages. In the context of medical devices, these disruptions can have particularly severe consequences, as delays in production and distribution can lead to shortages of essential medical equipment, potentially jeopardizing patient care.

In addition to global disruptions, companies must also contend with local challenges such as customs delays, import/export restrictions, and varying quality control standards in different regions. These challenges are compounded by the need to ensure the safe and timely delivery of highly sensitive medical products, which often require specialized packaging, temperature control, and storage conditions.

To address these challenges, many companies are rethinking their supply chain strategies by diversifying their supplier base, investing in digital tools for supply chain management, and building more resilient logistics networks. By adopting these strategies, companies can minimize the risk of disruptions and ensure the smooth flow of goods across borders.

5. Strategic Technological Management Approaches

In order to thrive in the global medical device market, companies must adopt a strategic approach to technological management. By focusing on research and development (R&D), optimizing digital tools and processes, and forming strategic global partnerships, companies can enhance their technological capabilities, drive innovation, and secure a competitive edge. In this section, we explore these approaches in detail, illustrating how each contributes to long-term success in the international market.

5.1. R&D Investment and Innovation

Research and development (R&D) is the cornerstone of technological advancement in the medical device industry. Innovation in this sector is not only driven by the need to improve healthcare outcomes but also by the ever-increasing demand for more efficient, safer, and cost-effective solutions. As such, R&D investment is essential for companies seeking to stay ahead of the competition and navigate the rapidly evolving market landscape.

By investing in R&D, companies can develop new technologies, improve existing products, and create more tailored solutions for diverse healthcare needs. R&D also facilitates compliance with regulatory requirements, as many new devices require rigorous testing and validation before they can enter the market. The ability to innovate not only opens up opportunities for market differentiation but also allows companies to respond quickly to emerging trends, such as personalized medicine, telemedicine, and minimally invasive procedures.

To maximize the impact of R&D, medical device companies should prioritize a strategic approach that focuses on collaboration with universities, research institutions, and healthcare providers. By aligning their R&D goals with the latest advancements in medical science and technology, companies can ensure that their innovations address real-world needs and have the potential to drive significant improvements in patient care.

5.2. Digital Tools and Process Optimization

In today's digital age, the effective use of digital tools and technologies is a critical element of technological management. Companies that leverage digital tools to optimize their processes can enhance efficiency, reduce costs, and improve overall product quality. The integration of technologies such as artificial intelligence (AI), machine learning (ML), and the Internet of Things (IoT) in the development and manufacturing of medical devices has revolutionized the industry, offering new ways to monitor and improve product performance.

AI and ML, for example, are increasingly being used for predictive maintenance, quality control, and data analysis in medical device production. These technologies can help companies identify potential issues before they become significant problems, ensuring that products meet the highest standards of quality and safety. Additionally, IoT-enabled devices allow for real-time data collection, enabling better decision-making and enhancing the ability to monitor devices once they are in use.

Process optimization, powered by digital tools, extends beyond the production floor. Supply chain management, regulatory compliance tracking, and customer support systems can all benefit from the integration of digital technologies. By streamlining operations, companies can reduce lead times, improve responsiveness to market demands, and enhance their ability to scale operations across multiple regions.

As illustrated in Table 2, the various digital tools and process optimization strategies are fundamental to achieving enhanced operational efficiency, reduced costs, and improved product quality.

Table 2. Strategic Technological Management Approaches for Medical Device Companies.

Approach	Key Focus	Strategic Impact
R&D Investment and Innovation	Focusing on new product development and enhancing existing products.	Drives product differentiation, improves market position, ensures compliance.
Digital Tools and Process Optimization	Leveraging AI, IoT, and ML to enhance product quality, process efficiency, and operational scalability.	Reduces costs, improves quality control, accelerates production timelines.
Global Partnerships and Alliances	Collaborating with local partners, healthcare providers, and global technology firms.	Facilitates market entry, fosters innovation, enhances product adoption.

5.3. Global Partnerships and Alliances

In a globalized market, forming strategic partnerships and alliances is essential for companies seeking to expand their reach and leverage external expertise. Collaborations with other companies, healthcare providers, and research institutions can open up new avenues for innovation, market expansion, and resource sharing.

For medical device companies, partnerships with local organizations in key international markets can be particularly valuable. These partnerships provide valuable insights into local regulatory environments, market trends, and customer preferences, which can help companies tailor their products and strategies to specific regions. Furthermore, partnerships with healthcare providers enable companies to conduct joint research, validate product efficacy, and improve the overall adoption of their technologies in diverse healthcare systems.

In addition, alliances with global technology firms can facilitate the integration of cutting-edge technologies into medical device products, such as cloud computing, big data analytics, and advanced robotics. These collaborations enable companies to stay at the forefront of technological innovation while also benefiting from the expertise and resources of their partners.

To summarize these strategic approaches, companies can maximize their competitive advantage by ensuring that their R&D, digital optimization, and global partnerships are seamlessly integrated and aligned with their long-term business objectives.

6. Case Studies

In this chapter, we present two case studies of medical device companies that have successfully applied strategic technological management approaches. These case studies offer valuable insights into how companies can leverage R&D, digital transformation, and strategic alliances to overcome market challenges and achieve sustainable growth in the international medical device market.

6.1. Company A: Innovation-Driven Market Expansion

Company A, a leading player in the medical device industry, has successfully expanded its market presence globally by prioritizing innovation in product development. The company focuses heavily on R&D and has developed a range of cutting-edge technologies, including advanced diagnostic tools and minimally invasive surgical devices, which have allowed it to differentiate itself from competitors.

The company's strategy is rooted in collaboration with leading research institutions and healthcare providers, enabling it to stay ahead of medical trends and deliver solutions that address pressing healthcare needs. For instance, Company A's partnership with a renowned university resulted in the co-development of a smart diagnostic platform powered by AI, capable of detecting early-stage diseases with unprecedented accuracy.

This focus on innovation has not only helped Company A gain a competitive advantage in existing markets but also enabled it to expand into new, high-demand regions such as Southeast Asia and Latin America. By leveraging global partnerships and maintaining a commitment to R&D, Company A has successfully adapted to varying regional needs and regulations, thereby driving its growth and success on an international scale.

6.2. Company B: Navigating Regulatory Hurdles

Company B, a prominent manufacturer of implantable medical devices, has faced significant regulatory hurdles in its expansion efforts, particularly when entering the European and Asian markets. Unlike Company A, Company B operates in a highly regulated environment, where each market presents unique challenges in terms of compliance with local laws and approval processes.

In order to navigate these regulatory barriers, Company B adopted a strategic approach to technological management by investing in regulatory affairs teams and establishing a robust framework for product testing and documentation. The company has formed strategic alliances with local regulatory consultants and has closely aligned its product development process with international standards, such as ISO 13485 for medical device quality management systems.

Moreover, Company B uses advanced digital tools for regulatory compliance tracking, allowing it to monitor the status of approval processes in real-time across multiple regions. This has significantly reduced delays in product launches and ensured that the company maintains a strong position in international markets despite the complexities of regulatory compliance.

6.3. Synthesis and Insights

The case studies of Company A and Company B illustrate the diverse ways in which medical device companies can leverage technological management strategies to address challenges and seize opportunities in the global market. Both companies have demonstrated the importance of integrating innovation, regulatory compliance, and strategic partnerships into their overall business models.

Company A's success highlights the power of R&D investment and innovation in driving market expansion, while Company B's experience underscores the critical role of navigating regulatory challenges to ensure sustained growth in international markets. Both companies have embraced digital transformation and collaboration as key components of their strategies, allowing them to enhance efficiency, improve product quality, and respond to regional market demands.

These case studies offer valuable lessons for other medical device companies seeking to expand internationally. By adopting a balanced approach that incorporates innovation, regulatory preparedness, and strategic alliances, companies can enhance their competitiveness, mitigate risks, and achieve long-term success in the global medical device industry.

7. Conclusion and Recommendations

7.1. Summary of Key Insights

This study has examined how effective technological management can empower medical device companies to strengthen their overseas trade performance. By reviewing current industry dynamics, identifying key technological trends, and analyzing practical management strategies, several critical insights have emerged.

First, the medical device industry is increasingly shaped by rapid technological innovation, heightened global competition, and growing regulatory complexity. In this environment, strategic technological management serves as a crucial enabler for sustained international competitiveness. Second, the integration of robust R&D initiatives, adoption of digital technologies, and formation of global partnerships are essential strategies for overcoming cross-border challenges such as regulatory compliance, intellectual property protection, and supply chain disruptions. Third, through the case studies, it becomes clear that companies who proactively manage technology across all levels — product development, regulatory affairs, and operational efficiency — are better positioned to expand into new markets and maintain long-term performance.

7.2. Managerial and Policy Recommendations

For industry managers, the following recommendations are proposed:

- 1) Embed technology leadership at the core of corporate strategy: Firms should institutionalize technological foresight and innovation management to guide international expansion plans.
- 2) Strengthen cross-functional R&D teams: R&D efforts should be interdisciplinary, combining engineering, regulatory, and market knowledge to ensure globally viable product pipelines.
- 3) Invest in regulatory intelligence systems: To proactively navigate foreign regulations, companies should deploy digital tools to track, simulate, and adapt to changing compliance landscapes.
- 4) Foster global alliances strategically: Collaborative ventures with local partners, universities, and hospitals can de-risk market entry and provide valuable insights into regional needs.

For policy-makers and regulators, the following considerations are relevant:

- 1) Facilitate international harmonization of regulatory standards to reduce entry barriers and encourage the global flow of medical technology.
- 2) Support SMEs and mid-sized firms with digital transformation grants, training in IP strategy, and export-readiness programs.
- 3) Encourage public-private partnerships that promote innovation hubs where research institutions and medtech firms can co-develop scalable technologies.

7.3. Future Research Directions

While this paper provides a conceptual and practice-oriented framework for understanding technological management in medical device companies, several avenues remain open for future inquiry:

- 1) Empirical validation: Future research could employ quantitative methods (e.g., surveys or panel data) to statistically test the relationship between technological management practices and overseas performance.
- 2) Regional focus studies: Comparative studies across different regulatory environments (e.g., EU, ASEAN, Latin America) could uncover nuanced barriers and enablers.
- 3) SMEs and startups: Given that smaller firms face resource constraints, future work could explore how lean technological strategies or incubator ecosystems impact their global performance.
- 4) Sustainability integration: As environmental standards gain prominence, future research should examine how green technological management influences both compliance and trade potential.

In conclusion, effective technological management is not merely a support function – it is a strategic imperative for medical device companies aiming to thrive in international markets. By embracing innovation, digital agility, and cross-border collaboration, firms can not only overcome trade barriers but also lead the next wave of healthcare transformation globally.

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