Chapter 10
Strategic Planning in Medical Device Innovation: Challenges and Opportunities

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ABSTRACT

This work explores strategic planning in medical device innovation, ensuring that technological and product advancements align with market needs, regulations, and company goals. It addresses a range of decisions and practices designed to ensure that innovation responds not only to technical and regulatory requirements but also has a positive impact on health and business sustainability. The study delves into the strategy of medical device innovation, examining the planning and execution processes aimed at ensuring technological innovation results in viable, effective products that meet the needs of the market and healthcare systems.

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1. INTRODUCTION TO STRATEGIC PLANNING IN MEDICAL DEVICE INNOVATION

Strategic planning in medical device innovation is essential for the development and success of this sector. It is crucial to understand and anticipate market needs, as well as to be prepared for emerging challenges and opportunities. This planning goes beyond merely defining goals and objectives; it involves a comprehensive analysis of internal and external environments, identifying necessary resources, and establishing clear and sustainable strategies for achieving success. (Santos et al., 2022; Oliveira, 2021; de Vianna Tiné, 2024).

Strategic planning in the medical device industry refers to the process of setting long-term objectives, identifying the actions required to achieve them, and efficiently allocating resources. In this industry, the process is critical as innovation and the development of quality products are fundamental for improving healthcare. The relevance of strategic planning lies in its ability to guide companies in the right direction, enabling them to anticipate and effectively respond to market changes and consumer needs. (Toni, 2021; Guedes et al., 2022; Abreu, 2020; Farias, 2022).

Innovation in the medical device industry is crucial for driving significant advancements in treating and managing medical conditions. The constant technological evolution, combined with the need for safer and more effective solutions, makes innovation a cornerstone of this sector. The synergy between strategic planning and innovation enables companies to develop medical devices that meet the needs of patients, doctors, and healthcare professionals efficiently and ethically, thus contributing to the overall improvement of healthcare systems. (Lube Filho, 2023; Souza et al., 2024; Fernandes, 2023).

Strategic planning is a process aimed at defining a company's goals and objectives, as well as the strategies to achieve them. It is a fundamental tool for business management, allowing companies to anticipate scenarios and make more informed decisions. During the 1960s and 1970s, businesses began adopting formal strategic plans, following them over the medium and long term, which highlights the growing importance of this process in the business world. (Pereira, 2023; Paço & Casaca; Loural et al., 2023).

Following World War II, strategic planning began gaining prominence in the business context, consolidating its importance in subsequent decades. In 1965, Ansoff's normative model of strategic planning marked a significant milestone while also revealing the challenges companies face in its implementation. Since then, the concept has evolved and been approached from various perspectives, keeping pace with transformations in the business environment. (Farias-UFRRJ; Elias, 2024; Poubel, 2022).