

CHAPTER

5

BIOMEDICAL DEVICE DEVELOPMENT

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5.1 INTRODUCTION

Most businesses rely on their capacity to swiftly and efficiently recognise client needs and develop low-cost products to suit those demands to be financially successful. Something that a company sells to its customers is called a product. The series of actions that start with identifying a market opportunity and conclude with the development, marketing, and distribution of a product is known as product development. Products that can be manufactured and sold financially are the outcome of a satisfactory product development process, although profitability is frequently challenging to evaluate immediately and clearly. We frequently employ five distinct dimensions, all connected to profit, when evaluating the effectiveness of a product development endeavour.

5.1.1 Quality of the Product

To what extent does the development effort yield a high-quality product? Does it satisfy the client needs? Is it dependable and strong? The best indicators of product quality are its market share and the willingness of its customers to pay.

5.1.2 Cost of the Product

What is the product manufacturing cost? The cost of manufacturing every single piece of the product also includes the additional expense of purchasing necessary equipment and tools. The product cost determines the company profit margin at a specific price and sales volume.

5.1.3 Time Needed for Development

How soon did the group finish working on the product? The length of development determines how quickly the team efforts provide financial rewards and how well the company can adjust to changes in the market and technological breakthroughs.

5.1.4 Cost of the Development

How much money did the company have to invest in creating the product? Typically, development costs account for a significant portion of the capital needed to turn a profit.

5.1.5 Enhancement Potential

Being involved in a project for product development has the team and the company more equipped to create future products? The company capacity to produce items more efficiently and economically in the future is one of its advantages.

The medical device development process requires the integration of engineering and medical knowledge and expertise. Lack of communication, priorities that are out of alignment, and disparities in work styles across various areas make such an integration challenging. Medical device development also involves unique characteristics that add to the process complexity, including a high degree of regulation, the use of many technologies at the same time, and varying end-user requirements. Furthermore, the risks that these medical devices pose to

users are classified into three categories: Low, medium, and high. This increases the complexity of these devices development processes, which differ according to the degree of risk involved.

The process of developing a medical device is intricate and time-consuming, requiring the cooperation of multiple teams, occasionally with conflicting demands as per Ahmad and Wasim (2023), as well as a variety of expertise and abilities, including those in design, healthcare, engineering, ergonomics, physiotherapy, occupational therapy, and sociological research (Moseley et al., 2023). Successful new solution proposals require this interdisciplinary integration, which adds value. However, due to things like poor communication channels, conflicting priorities, and different work styles, it is far more difficult to execute (Nwulu et al., 2023).

As of right now, the product development process acknowledges the idea of integrated product development, where experts from other fields collaborate on a new product project (Marzi et al., 2023). A few unique characteristics of medical device development contribute to the process complexity, including:

- (1) Regulation: The medical device industry is heavily regulated. In addition, rules are constantly changing.
- (2) Technology: The medical device industry is very innovative, and new products typically incorporate several technologies, including electronics, materials science, mechanics, software, and so on; and
- (3) Users: The medical device industry includes a variety of users, including patients, carers, and medical professionals.

5.2 CONCEPT DEVELOPMENT

The concept creation process typically includes many related tasks, as shown in Figure 5.1 with dashed arrows illustrate that product development progress is unpredictable. The team may need to revert to an earlier activity and repeat it before moving on at virtually any point due to new knowledge or lessons gained.