

## The Development of Medical Devices in Foreign Markets

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### Introduction

To date, the medical device industry in the USA encompasses revenues around \$110 billion, about one-third of the \$350 billion global market [1], offering significant opportunities in terms of market growth, economic diversity, employment expansion, and export. Innovative medical devices can also significantly impact the workforce productivity by improving patients' quality of life, or accelerating their ability to return to work after a medical leave.

The development of medical devices is a complex segment of the healthcare industry, as it requires convergence of expertise from multiple fields beyond life sciences and engineering [2]. Although Northern America and Europe still dominate the global market, new opportunities for medical technology development are emerging in Asia and South America following the improvement of their healthcare services. Thus, investors and senior leadership often expect a "global strategy" as part of the business plan of a new device. However, even if the penetration of foreign markets is clearly advisable, this process faces multiple hurdles and investment risks that may hamper a successful outcome. Below we discuss some key issues and suggestions to foster the expansion of new medical technologies in foreign markets, and the key role played by outsourcing partners, product differentiation and regulatory environments.

### Outsourcing

To control the cost of products and provide top-quality support to consumers, leading companies are increasingly outsourcing selected functions - such as labor, manufacturing and services - to external providers. This practice allows companies to concentrate on the development of their core business. Also, contract manufacturing organizations, and in particular local manufacturers, can expedite the entry in to emerging markets and lower the average sale price of a specific technology. Indeed, the outsourced team can play a role in the product development cycle by making recommendations for key additions to the core product, or bringing in specific knowledge of local markets and/or building technical support [3].

Marketing support from local doctors, scientists and patients is also critical to encourage commercial adoption and distribution of new technologies in a new market. This is particularly important for devices that have moved from hospital labs to the hands of patients, such as heart rate monitors, pedometers, etc. In addition, distribution partners can easily engage these communities, provide more marketing mileage by influencing new buyers, and complete the device registration in the intended country.

Collaborations with local scientific communities and access to patient data can improve the device design and function, as well as its post-marketing surveillance to further validate safety and efficacy. On

the other hand, the penetration of new markets may pose several challenges in this regard, including the management of data privacy and security, as well as interpreting the heterogeneity of patient data resulting from the variety of disease course and symptoms across populations that differ in culture, food habits and genetic backgrounds.

### Software development as a "differentiator"

The development of new software platforms provides unique opportunities to expand the market of medical devices given the ease and speed at which software applications can be changed for different uses.

A good example is offered by portable ultrasound technologies, generally used for the diagnosis of diseases affecting multiple body organs. Traditionally, ultrasound algorithms converting sound waves into visual representations are implemented through complex and expensive hardware. The same functionality can be now achieved via new software with several advantages. Indeed, while the traditional "hardware-based" approach requires the complete re-development and validation of the device before its market release, the software-based approach allows feature-by-feature releases through software upgrades without changing the base platform. Although a flip side of this approach is the need to go through multiple regulatory approvals, the time to market is generally significantly faster.

Telemedicine is another example where the scope of use of an existing device can be expanded through a software layer over a USB or Bluetooth technology. This approach enables applications available on smart phones to interact with medical devices and facilitate data transfer to servers accessible by a healthcare provider. Through outsourcing partners, medical device manufacturers can also leverage the implementation of protocol stacks, a complete set of network protocol layers that allow computers to connect and transmit data to one another.

These technologies are becoming increasingly relevant to emerging economies as they allow data exchange between rural areas and healthcare providers available only in major cities.

### Regulatory Challenges

Understanding geographical differences in regulatory requirements and healthcare delivery is critical when planning a global strategy. Compliance with industry standards, environmental hazards, quality control, labeling and import requirements, may slow down the development of medical devices and often force manufacturing companies to redesign their products to meet local specifications. Companies devote a significant amount of time and resources to understand the composition of materials used to manufacture their devices, screen the supply chain and maintain compliance records [4].

As this activity is not a core area of expertise for manufacturers, outsourcing these functions to organizations focusing on regulatory compliance within their territories is a more cost-effective approach that can avoid mistakes and unnecessary delays.

A careful analysis of local reimbursement practices and health economics is essential to understand whether a product can fit into an existing code that guarantees adequate payment and, consequently, its affordability in the intended market.

In addition, products providing disruptive technologies may experience more regulatory challenges than devices offering only variants or increments of existing technologies. In the former case, interaction with local authorities and key clinical practitioners may be necessary. Finally, intellectual property coverage should be carefully evaluated. Often, in foreign markets, a proactive step such as trademark registration can significantly increase the protection of proprietary assets [5].

In conclusion, the medical devices sector offers significant economic opportunities in terms of sustained market growth and economic expansion, not to mention the wide range of associated healthcare benefits. Thus, federal and private investments directed to device expansion in global markets would be valuable not only to support this

sector in the USA, but also to sustain the development of emerging economies. Adding a global strategy into the device development lifecycle can attract investors and significantly contribute to the success of a new product and its ability to generate revenues. Positive outcomes, however, depend on a well-planned analysis of the healthcare economy across different geographical areas and on strong partnerships with local manufacturers, physicians, distributors, and advisers with deep knowledge of the respective regulatory landscapes.

## Reference

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