

# **TATA ELXSI**

5 Emerging Markets for Medical Device Manufacturers



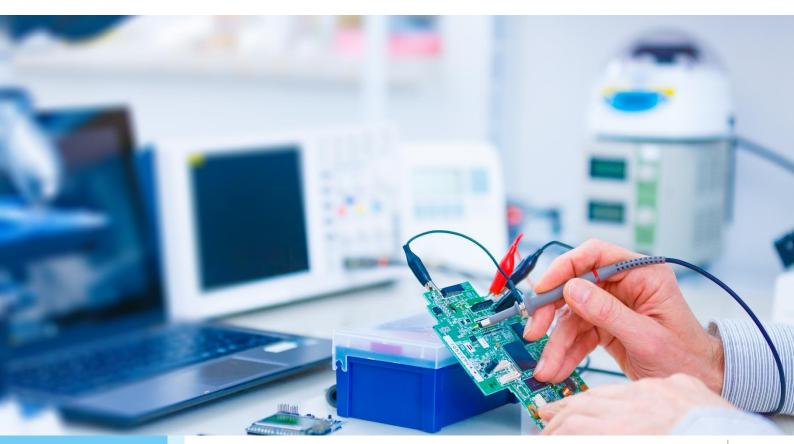
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### **ABSTRACT**

The demand for high-quality healthcare services and sophisticated medical devices is continuing to rise in the emerging markets owing to rising disposable income, increasing medical insurance penetration, growing medical tourism industry, and a reformed healthcare system driven by national governments. This ongoing economic development in the emerging nations presents lucrative and abundant opportunities for medtech organizations and call for medical device manufacturers to tap into the thriving markets with tailor-made, targeted, and user-defined products. However, manufacturers need to target each emerging market with a dedicated and commensurable entry strategy that holistically seizes the essence of the user needs, local infrastructure, and manufacturing capabilities. Additionally, foreign organizations would also need to consider factors such as the regulatory approval process, permitted distribution and sales channels, and the ease of collaboration with domestic value chain stakeholders to create a successful entry strategy. While the ambiguous regulations, IP laws, and the sociopolitical environment in the emerging nations surely act as a deterrent for foreign organizations, however, if approached with a carefully planned and meticulously crafted strategy, the pay-offs can be monumental for the coming decades.



## INTRODUCTION

The global medical device industry is witnessing a steady and robust growth fueled by a range of factors such as the rising prevalence of chronic diseases, increasing aging population, and unforeseen demand for digital and connected devices, especially during the pandemic.

In 2018, the global medical device industry reached a value of USD 425.2 billion and was expected to grow at a CAGR of 5.4% to reach around 612.7 billion in 2025. The industry is dominated primarily by developed countries. The US and Europe are the top two medical technology markets making up 40% and 27% of the global medical device industry respectively in 2017. Consequently, for decades, the manufacturers have been focusing on designing and developing devices or medical equipment based on the needs of the developed markets and subsequently launching the same products in emerging countries with few alterations. However, an efficient way for the manufacturers would be to develop country or region-specific brand new cost-effective products. For e.g., GE healthcare designed a compact and portable ultrasound machine for the Chinese market, costing merely USD 15,000 compared to over USD 100,000 for their high-end markets. The machine was an instant hit in China due to its affordability and portability; and it also created new sales opportunities for GE healthcare in developed countries.

As most of the emerging economies continue on high growth trajectories, this would be an excellent opportunity for the medical device companies to strive for and deliver technologically advanced, innovative yet affordable solutions that cater to the specific needs of the emerging markets.

## MedTech Industry in Emerging Economies – Market Overview

#### Top 5 emerging markets

As per United Nations Industrial Development Organization (UNIDO), Brazil, Russia, India, China, and South Africa, or BRICS, are not only considered the major emerging economies in the world due to their rapid growth but are also setting a benchmark for the industrialized countries.

During the sixth BRICS Summit in 2014, these countries have established the New Development Bank (NDB), also formerly referred to as the BRICS development bank, to support and sustain the development efforts in BRICS and other emerging nations.



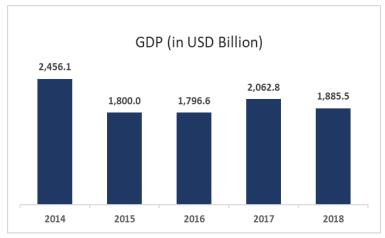
**BRICS Countries** 



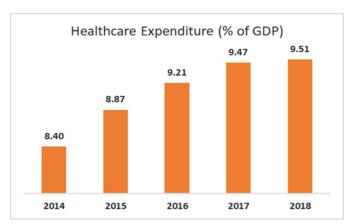
Below is the individual breakup of the economic condition and the healthcare sectors in the aforementioned emerging markets:

#### **Brazil**

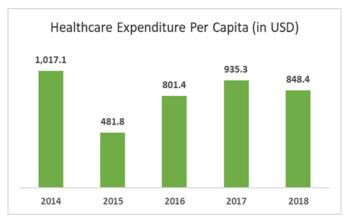
Brazil is the twelfth largest economy in the world by nominal Gross Domestic Product (GDP). As per the International Monetary Fund (IMF), Brazil's nominal GDP was USD 1.89 trillion in 2018.



Data Source: International Monetary Fund (IMF)



Data Source: World Health Organization (WHO)

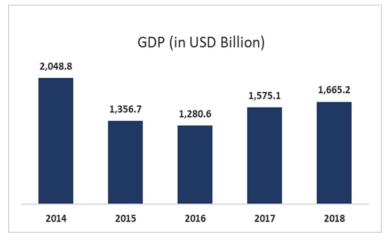


Data Source: World Health Organization (WHO)

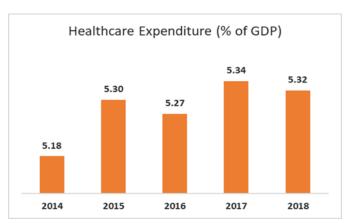
Brazil's healthcare market is the largest in Latin America. According to the World Health Organization Global Health Expenditure database, the country spent about 9.5% of its GDP on healthcare with a health expenditure of USD 848.4 per capita in 2018. The medical devices market in Brazil stood at approximately USD 10.5 billion in 2018. Imported medical devices make up 80% of the entire market with the US being the leading exporter representing about 29% of the total medical device imports.

#### Russia

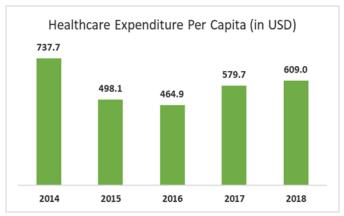
Russia's economy is the fifth-largest in Europe and eleventh largest in the world by nominal Gross Domestic Product (GDP). As per the International Monetary Fund (IMF), Russia's nominal GDP was USD 1.67 trillion in 2018.



Data Source: International Monetary Fund (IMF)



Data Source: World Health Organization (WHO)

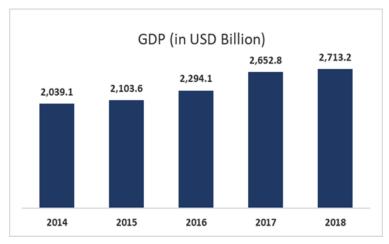


Data Source: World Health Organization (WHO)

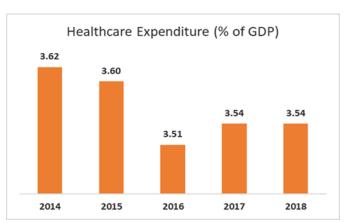
According to the World Health Organization Global Health Expenditure database, the Russian Federation spent about 5.3% of its GDP on healthcare with a health expenditure of USD 609.01 per capita in 2018. The medical technology market in Russia was valued at approximately EUR 3.8 billion in 2017 and is one of the largest in Central and Eastern Europe. Due to the rising demand for sophisticated medical devices and the shortage of domestic manufacturers, the Russian healthcare system relies primarily on imports with Germany, the US, and China being the leading suppliers.

#### India

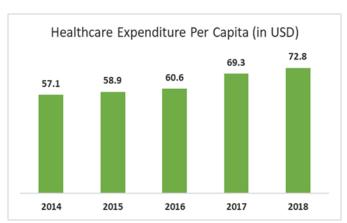
India's economy is the fifth-largest in the world by nominal Gross Domestic Product (GDP). As per the International Monetary Fund (IMF), India's nominal GDP was USD 2.71 trillion in 2018.



Data Source: International Monetary Fund (IMF)



Data Source: World Health Organization (WHO)

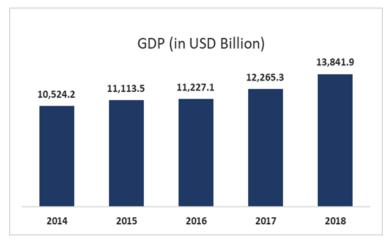


Data Source: World Health Organization (WHO)

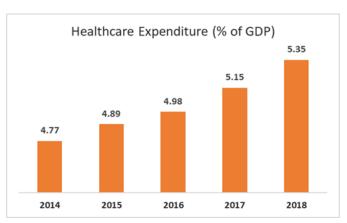
Healthcare is the fourth largest business sector in India, both in terms of revenue and employment. According to the World Health Organization Global Health Expenditure database, India spent about 3.5% of its GDP on healthcare with a health expenditure of USD 72.8 per capita in 2018. The medical device industry amounted to 4-5% of the Indian healthcare industry and was valued at USD 5.2 billion in 2017. It is further expected to reach USD 50 billion by 2025. India is highly dependent on medical devices import. About 75% of medical devices sold in India are imported from developed nations such as the US, Europe, etc. The government has taken initiatives such as lower customs duty, lenient regulatory environment, etc., for international manufacturers to encourage incoming trade.

#### China

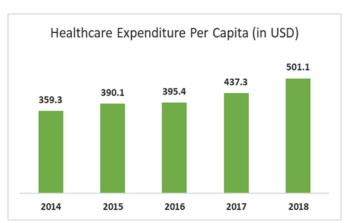
The economy of the People's Republic of China is the second-largest in the world by nominal Gross Domestic Product (GDP), second only to the US. As per the International Monetary Fund (IMF), China's nominal GDP was USD 13.8 trillion in 2018.



Data Source: International Monetary Fund (IMF)



Data Source: World Health Organization (WHO)

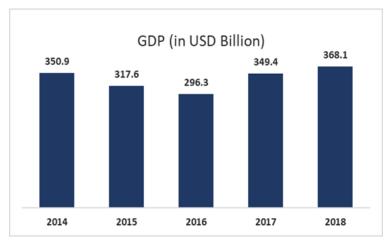


Data Source: World Health Organization (WHO)

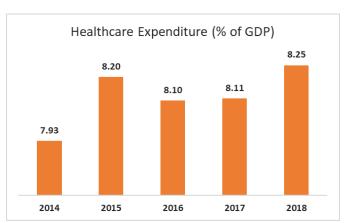
The healthcare sector in China is the second-largest in the world with USD 1.1 trillion in value in 2019 behind only the US. According to the World Health Organization Global Health Expenditure database, the country spent about 5.3% of its GDP on healthcare with a health expenditure of USD 501.06 per capita in 2018. The medical device industry in China had crossed USD 96 billion in 2019 from USD 54 billion in 2016, witnessing a growth of nearly 80% in 3 years. Although the Chinese medical technology market is dominated by the local manufacturers that supply low to mid-range products, the consumers still prefer reputed foreign companies for innovative high-tech devices.

#### South Africa

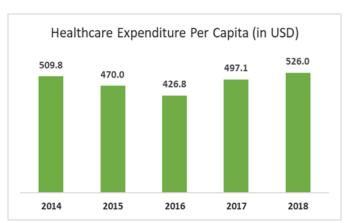
The economy of South Africa is the second-largest in Africa and ranks 43rd in the world by nominal Gross Domestic Product (GDP). As per the International Monetary Fund (IMF), South Africa's nominal GDP was USD 368.1 billion in 2018.



Data Source: International Monetary Fund (IMF)



Data Source: World Health Organization (WHO)



Data Source: World Health Organization (WHO)

The healthcare sector in South Africa is expected to advance at a CAGR of 4.7% during 2017-2022 to reach USD 37 billion by 2022 and USD 47.1 billion by 2027. According to the World Health Organization Global Health Expenditure database, South Africa spent about 8.3% of its GDP on healthcare with a health expenditure of USD 525.96 per capita in 2018. With the growing healthcare sector, the country's medical device market is also expected to grow at a CAGR of 8.9% from USD 1.3 billion in 2018 to USD 2.1 billion in 2024. As local production is limited mostly to consumables, South Africa relies heavily on the imports of medical devices dominated primarily by US-based suppliers. However, the buyers are now exploring Asian markets, such as China, for sourcing affordable yet high-tech equipment.

#### **Medical Technology Trends in Emerging Markets**

Some of the major trends that are transforming the medtech industry in the emerging markets are as discussed below:

#### Miniaturization of Devices

Miniaturization has evolved as a major trend in the medical device industry in recent years. From large to smaller to the smallest, the miniaturized components empower researchers and manufacturers to explore unique ideas and innovative design techniques. Emerging countries are also witnessing increasing demand for wearable, wireless, and sensor-based medical devices due to the rising incidences of lifestyle diseases such as obesity, diabetes, and heart problems, and the growing elderly population. Moreover, the widespread availability of low-cost medical device grade semiconductors that enable large-scale integration and reduce power consumption further facilitates the rapid growth of miniaturized medical devices in emerging geographies.

#### Emergence of Telemedicine

The emerging nations are witnessing a massive urban transformation due to rapidly growing economies, expanding metropolitan areas, and increasing population migration. However, a considerable part of the population still resides in rural areas. For e.g., according to the world bank 2019 data, the percentage of the rural population in Brazil, Russia, India, China, and South Africa is 13.2%, 25.4%, 65.5%, 39.6%, and 33.1% respectively. Similarly, the physicians available per thousand people in BRICS nations are 2.17, 4.01, 0.78, 1.98, and 0.91 respectively as per the World Bank 2017 data. This creates a huge healthcare accessibility problem for patients, healthcare providers, and the local governments. However, telemedicine initiatives are providing viable solutions to the dire need for remote access to care. Telemedicine as a technology can be applied to every medical specialty such as pathology, cardiac intensive care, dermatology, rheumatology, and many more essentially creating a virtual hospital for remotely located patients.



Furthermore, with the COVID-19 pandemic disrupting the global healthcare industry, doctors and care providers are turning to telemedicine solutions to provide patient care outside of conventional clinical settings, minimize the non-essential in-person visits, and optimize clinical staff utilization.

#### Device Connectivity and Data-driven Healthcare

Healthcare providers in emerging markets are exploring technologies that offer holistic solutions and applications that cater to multiple needs and demands. There is a pressing need for single unified platforms that can connect with various diagnostic and monitoring devices, with minimum effort, and support medical practitioners in streamlining root cause analysis and therapy planning over a short period. The lack of trained healthcare professionals and gaps in local healthcare infrastructure, further increase the demand for low-cost yet sophisticated systems that facilitate device connectivity and interoperability thus allowing users to have a one-stop solution for efficient data collection, management, and integration of medical devices. In addition, increasing access to medical insurance and individuals' capacity to spend have contributed to the rising demand for data-driven treatments tailored for specific patients, thus making precision medicine an achievable goal for the emerging markets.

#### **Growing Medtech Business in Emerging Markets**

A country's socio-economic, political, and regulatory climate has a tremendous impact on an organization's ability to establish its presence and grow in that market. In a highly regulated medtech industry, it becomes even more critical for the manufacturers to meticulously learn and understand the aforementioned factors, and accordingly strategize their market entry plans.

#### Business Environment

**Brazil** – Brazil ranks 124th in the World Bank's "Ease of Doing Business 2020" report. According to the world bank, the net inflow of FDI in Brazil peaked in 2011 with USD 102.4 billion in foreign investment. However, with a foreign investment of USD 69.1 billion in 2019, Brazil remains an attractive destination for global investors. The country also ranks no. 1 in Latin America and the Caribbean in terms of FDI inflow. In addition, the government passed a law in January 2015 allowing foreign companies to participate and invest in the Brazilian healthcare sector.

The National Health Surveillance Agency, or Anvisa, regulates the registration and commercialization of medical devices in Brazil.

Additionally, Anvisa is also part of the Medical Devices Single

Audit Program (MDSAP) with the US, Japan, Canada, and Australia being the other members. The program further streamlines the inspection process and expedites the approval of new products. However, registration certificates are granted only to local companies and foreign manufacturers, with no regional subsidiaries, generally rely on domestic distributors or dealers to establish their presence in Brazil.

**Russia** – Russia ranks 92nd in the World Bank's "Ease of Doing Business 2020" report. According to the world bank, the net inflow of FDI in the Russian Federation peaked in 2008 and 2013 with foreign investment of USD 74.7 billion and USD 69.2 billion respectively. With an influx of USD 8.7 billion, FDI fell drastically in 2018 but increased enormously in 2019, reaching USD 31.9.

Medical device registrations are regulated by Roszdravnadzor (RZN) in Russia.

The registration process poses several challenges, especially for a foreign manufacturer, as RZN only accepts local clinical and testing data for the approvals. Furthermore, foreign entities need to have a local subsidiary or a local authorized representative to submit the documents of registration to the RZN.

India – India ranks 63rd in the World Bank's "Ease of Doing Business 2020" report. According to the Department for Promotion of Industry and Internal Trade (DPIIT), India attracted a cumulative FDI inflow of USD 500.12 billion in the last two decades. In 2019, USD 50.6 billion worth of FDI came into the country, as per the world bank. The increasing inflow of FDI demonstrates the government's efforts to facilitate incoming business investments. Furthermore, FDI in the manufacturing of medical devices is allowed to the extent of 100% under the automatic route (without obtaining prior regulatory approval).

Central Drugs Standard Control Organization (CDSCO) is the national regulatory body for pharmaceuticals and medical devices in India. In addition to pharma regulations, it also manages manufacturing, import, sales, and after-sales of medical devices.



Overseas manufacturers rely on local sales subsidiaries or distributors to obtain a license for device sales and marketing in India.

China – China ranks 31st in the World Bank's "Ease of Doing Business 2020" report. According to the World Bank, the net FDI inflow in China reached USD 290.9 billion in 2013, however, dropped significantly since then to USD 155.8 billion in 2019. Nevertheless, as per the latest report released by the United Nations Conference on Trade and Development (UNCTAD), China became the largest recipient of FDI amidst the COVID-19 pandemic with foreign investment of about USD 163 billion in 2020. Furthermore, according to a new Foreign Investment Law (FIL) effective from January 2020, the government has facilitated an easier and more efficient application process for the medical device manufacturers setting up facilities in China.

National Medical Products Administration or NMPA manages the registrations and inspections of the medical devices in China. For devices not manufactured in China, companies need



to provide sample devices to NMPA for testing along with documents of approvals from other regions such as CE Mark, 510(k) letter, ISO 13485 certification, etc. NMPA also requires all the supporting documents to be translated into simplified Chinese

South Africa – South Africa ranks 84th in the World Bank's "Ease of Doing Business 2020" report. As per the World Bank, the net inflow of FDI in South Africa was USD 4.6 billion in 2019, witnessing a drop of about 20% from USD 5.5 billion in 2018. South African Health Products Regulatory Authority (SAHPRA) regulates medical and IVD devices in the country. All local and foreign manufacturers willing to sell their products in South Africa need to register their devices with SAHPRA. However, foreign companies need to have a local presence, such as a local subsidiary or an authorized domestic distributor, to approach and register with SAHPRA.

#### Intellectual Property Laws

All the 5-member states of BRICS are a member of the World Trade Organization (WTO). Each country's domestic legislation became compatible with WTO's Trade-Related Aspects of Intellectual Property (TRIPS) framework when they signed the agreement. The TRIPS agreement, which came into effect in January 1995, is an international legal agreement between all the WTO member states that sets minimum standards for various forms of Intellectual Property (IP) regulations and must be incorporated by the WTO member nations in their respective national legislations. However, despite the agreement, the implementation and subsequent enforcement of the same is a challenge for some of the member states. For example, countries such as Brazil and Russia struggle to enforce stringent IP laws due to ambiguous regulations and the high prevalence of corruption in government agencies. Furthermore, China is famously known for imitating products and business models from the developed countries. Nevertheless, the Chinese government is becoming more serious about protecting intellectual property rights as per the country's efforts to be associated with innovation.

# Opportunities and Challenges for the Medical Device Manufacturers in Emerging Markets

#### **Opportunities**

Surging Healthcare Expenditure – The government healthcare spending varies across the BRICS countries but growing steadily with the rapidly developing nations. The increasing healthcare investments are primarily driven by the growing GDP, aging population, and the rising prevalence of chronic diseases in the regions mentioned above. The surge in government expenditure in healthcare is expected to create new opportunities for market expansion and the growing private investments and funding in the sector will create many lucrative opportunities for various global and regional key players in this market.

Rising Medical Tourism – Emerging countries are witnessing significant growth in the number of foreign patients visiting major hospitals offering quality and standardized medical services. This influx of patients with higher affordability creates the market for premium devices. Remarkably low medical expenses and high-quality care make these countries the preferred destinations for overseas patients. For e.g., the cost of surgery in India is nearly one-tenth of the cost in developed countries. As per a report by the Federation of Indian Chambers of Commerce & Industry (FICCI), the medical tourism industry in India stands at nearly USD 9 billion and accounts for about 18% of the global medical tourism market. Brazil is another preferred destination for patients worldwide as the country hosts around 50,000 medical tourists every year. In addition to the BRICS nations, some other emerging economies that are popular for medical tourism are Thailand, Costa Rica, Mexico, Malaysia, and Singapore.

**New Potential Markets** – Due to the price-sensitive nature of the emerging markets, manufacturers are compelled to develop low-cost devices while meeting the highest quality standards of the medtech industry. These products are often designed to meet the unique requirements of the domestic market and frequently develop a niche in other countries and regions. As a result, emerging countries have recorded significant growth in medical device exports over the last few years.

According to the General Administration of Customs (GAC), exports of medical devices from China increased by over 40% in 2020 as compared to the previous year. Similarly, the Indian export of medical equipment and consumables increased by about 7.2% over the same period. Furthermore, as manufacturers in emerging markets grow and export their products, often at much lower prices, it becomes challenging for the incumbent firms to stay competitive in that niche segment.

#### **Challenges**

Government Prioritizing Domestic Manufacturers – In most of the emerging countries, governments not only offer subsidies and incentives but also favor local medical device manufacturers for government orders to encourage and boost domestic manufacturing, for e.g., in Russia's public healthcare system, foreign manufacturers are not allowed to participate in government tenders for selected medical devices. Similarly, the Chinese government frequently compels hospitals and healthcare facilities to favor equipment and devices that are 'made in China' by Chinese companies. Furthermore, as discussed in the section above, all foreign manufacturers need a domestic entity to register and sell medical devices in the BRICS nations.

**Established Local Players** – While it has already been established in the sections above that most of the BRICS and other emerging economies rely primarily on the import of medical devices to meet the rising demand, however, many of these countries have highly fragmented domestic industry comprising of multiple indigenous manufacturers that have carved a niche for themselves by offering low to mid-range devices and disposables for price-sensitive consumers and healthcare providers.

Affording High-End Technology Devices – As the name suggests, emerging countries, while growing expeditiously are still in the developing phase and a significant portion of the population in these countries belong to the low and middle-income classes. Consequently, hospitals and healthcare providers need to be cautious about the price-sensitive nature of the general populace while making purchasing decisions.



For e.g., major hospitals in metropolitan cities are driven primarily by factors such as quality and brand name while choosing a device. In contrast, smaller hospitals, clinics, and healthcare providers in suburban and rural areas typically opt for low-cost and reasonably priced products.

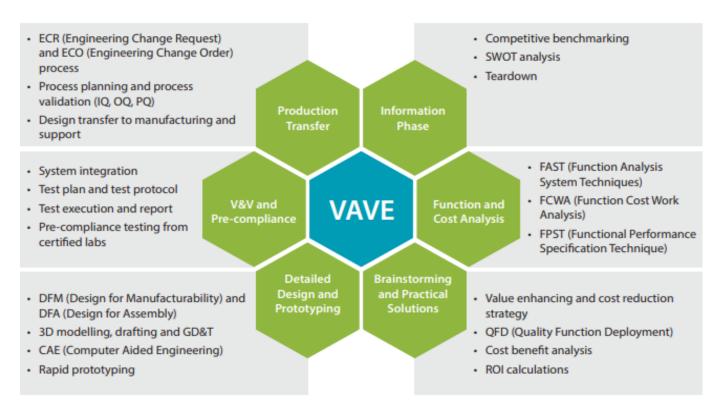


## Medical Device Engineering for Emerging Markets

Many medtech organizations design and develop their products as per the needs of the developed countries and introduce the same in emerging markets with minor modifications. However, as most emerging countries have larger populations and lower per capita health expenditure, they are generally impervious to the factors affecting medical device design in the developed world.

Therefore, in order to deliver more market-oriented products, medical device manufacturers need to go back to the drawing board and brainstorm designs that are more in line with the needs of the domestic markets. Another efficient approach for the manufacturers would be to revisit the existing product line and explore the opportunities to maintain benchmarked product quality and performance while aligning product cost in accordance with regional price sensitivity. Companies can further identify usage gaps and incorporate user feedback to launch technologically advanced products in the market. This process is generally termed Value Analysis and Value Engineering (VAVE) methodology which systematically drives down the product cost while maintaining or improving performance and quality requirements.





Tata Elxsi Value Analysis and Value Engineering (TEVAVE) Methodology

Furthermore, devices designed for emerging markets could potentially be well suited for the issues that ultimately affect every market.

## CONCLUSION

Emerging markets are witnessing remarkable economic advancements, which presents exciting and lucrative growth opportunities for the global medical device manufacturers. Moreover, business-friendly policies and strengthening intellectual property laws in the emerging economies such as BRICS nations and medical technology trends such as device miniaturization, the emergence of telemedicine, and increasing demand for data-driven healthcare solutions are transforming the MedTech industry in the emerging countries. Although there are some challenges for non-native companies such as governments prioritizing domestic manufacturers, established local players, and the price-sensitive nature of the consumers, there are many opportunities as well in terms of increasing public & private healthcare spending, rising medical tourism, and new potential markets that can be targeted with the high quality yet low-cost products designed for emerging countries.

Therefore, instead of recycling the designs for existing products, medical device manufacturers must understand the local voice of the customer and offer customized solutions that cater to the specific needs of the emerging markets.



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#### **ABOUT TATA ELXSI**

Tata Elxsi, a part of Tata Group, is among the world's leading providers of design, engineering, and regulatory compliance services. With 15+ years of experience in catering to medical device and healthcare companies, Tata Elxsi has built a comprehensive services and solutions portfolio that adds value at every stage of the customer's product development lifecycle. Tata Elxsi is an established name in technology consulting, new product design, development, verification and validation, and regulatory compliance services.

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