

MEDICAL DEVICES AND IN VITRO DIAGNOSTIC OPPORTUNITIES AND CHALLENGES: GLOBAL AND INDIA PERSPECTIVE

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The first manufactured medical device can be traced back to approximately 7000 BC when drilling of human teeth in vitro was carried out in Balochistan, part of then India and now Pakistan where flint tipped drills were used by dentists. Medical devices (MDs) are a unique combination of components which may include combinations of software, hardware, electronic, IoT components, materials and drugs to achieve unique function for end users. MDs is an extremely expansive term encompassing a wide range of devices intended for healthcare, right from scalpels to pacemakers intended for permanent implantation. Access to good quality, cost effective and the right medical products is of utmost importance for a healthier Indian and global population.

India is the fourth largest market of [medical devices](#) in Asia and counted amongst the top 20 markets in the world. In 2020, the total market was estimated to be US\$5.2 billion. Even after the grave importance of these products, India had no regulation until very recently when the Indian Medical Device Rules was first introduced in 2017 and became effective from 1st Jan 2018- a risk-based regulation at par with the global harmonization task force. It has sufficient statutory provisions to promote domestic manufacturing and to regulate imports. The pandemic was also an eye-opener which shed light on the inadequacies of the Indian healthcare sector. Thus, the health ministry has now also released a draft "New Drugs, [Medical Devices](#) and Cosmetics Bill 2022" for public consultation which may be in force from 2023.

Baby Steps taken by the Government of India

The Indian healthcare industry is still growing steadily and has evolved significantly in a very short period of time; the market is currently established at \$5.5billion and is growing yearly at a steady rate of 15% CAGR, significantly higher than the global trend.

There have been several initiatives made by the Indian Government since realising the potential of this field. The Government has approved four [medical device](#) parks to enable development of a healthy MedTech ecosystem and support medical technology innovation and manufacturing. A Production Linked Incentive (PLI) scheme was also introduced as part of a Make in India drive to make India a worldwide MD & IVD manufacturing powerhouse; by 2025 the overall Indian market is estimated to be \$50billion which is a great example for the potential growth opportunities this industry can provide within India.

Drivers of Indian Medical Device Market Growth

Increasing population and higher life expectancy anticipated, rise in diseases within the lower age groups, growing health insurance market, relatively low cost of medical care and increasing medical tourism are strong drivers of growth. The [Covid- 19](#) pandemic also unearthed numerous opportunities that were unexplored before. Advanced and complicated medical systems have now even been adopted by smaller [hospitals](#) and clinics, demand for at home [medical devices](#) increased and production sprung up in the country. Furthermore, policy support and incentives by the govt., led to vibrant medical start-up ecosystem.

As bright as the endeavour might sound, manufacturing [medical devices](#) can be a tasking process with a lot of challenges on the way. It is important to recognise these challenges and tide over them.

Challenges Faced by the Industry

The pandemic also brought in several challenges with it. Global supply chain in every industry was crippled and it did not even leave the healthcare industry behind. At the same time, demand for [medical devices](#) rose creating a huge gap between the demand and supply of the products. A rise in raw materials also further increased the cost of manufacturing of these products which were already high following a rise in demand. The Government's focus on *Atmanirbharta* is also impressive, but the allocation of the budget on healthcare is amongst the lowest in India. Positive efforts towards substantial changes will need good financial and policy support from them.

The Way Forward

A broad skill set is required by MDs experts: Diverse capabilities, innovation-led mind-set, device and biomedical interface knowledge, IPR, device and combination products regulations, auditing, quality management systems (QMS), etc. With the understanding of various challenges and opportunities for MedTech business sector, companies rely for its growth on experts in various fields such as engineering, tech, health care and pharmacy professionals. Furthermore, there is a need for educational programs to bridge the huge gap between formal education and requirements of the industry. AI applications, wearable and remote monitoring devices and electronic health records (EHR) are emerging trends that can capture this market well. Consumer awareness, higher disposable income, 3D printing and product innovation are also some key industry trends.

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