

VIEW POINT



Indian Medical Device Industry - Current State & Opportunities for Growth



- Dinesh Peter, Life Sciences and Services, Infosys Consulting

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Introduction

The Indian medical device market is worth well over the \$3 billion dollar mark and is on a path of lower double digit growth as of 2014. Despite the presence of a growth-oriented market with huge potential, the Indian medical device industry is replete with challenges.



Headwinds in Indian market

- Archaic regulatory standards
- Inadequate quality standards and non-compliance tarnish image of Indian-made products
- High import dependency
- Unfavorable duty structure whereby devices manufactured in India become more expensive than low-priced imported ones
- Lack of tax incentives to promote indigenous manufacturing

- Meagre government funding to promote innovation
- Lack of local talent

In such a scenario where the market is not tapped into adequately due to inherent challenges, companies have the opportunity to capitalize on the market by adopting the following strategies.

Strategies to capture Indian market

- Understand dynamics of the market,

local sentiments, challenges and opportunities better

- Partner with domestic technology companies for an efficient market entry and market growth strategy
- Revolutionize domestic salesforce
- Add more value to healthcare providers and patients alike, not just through products, but also services wrapped around the product

Subsequent sections will expand on each of the above pointers.

Understanding the Indian market

Medical device industry is influenced heavily by factors such as the country's GDP, overall healthcare expenditure, level of public spend on healthcare compared to private sector, population's disease pattern-linked demand for treatment options, population's awareness of treatment options and their reception to certain device-based therapy, healthcare providers, regulatory environment, taxation and reimbursement options.

Economics-based factors

A World Bank estimation reveals that India typically spends only 1% of its overall GDP on public health (accounting for recurrent and capital spending from government budgets, external borrowings, grants and social health insurance funds) [1].



Fig 1. A mapping of the major factors that affect the Indian medical device industry

Countries	Public healthcare expenditure as a % of GDP	GDP (in trillions of USD)	Population size (in millions)
Bangladesh	1.2	0.13	155
Indonesia	1.2	0.88	247
India	1.3	1.86	1,237
Singapore	1.7	0.29	5
Malaysia	2.2	0.30	29
Vietnam	2.8	0.14	89
Thailand	3	0.36	67
China	3	8.23	1,351
Japan	8.3	5.95	128
United States	8.3	16.16	314

Table 1. Country-specific population and economic data for 2012 [1]

To put things in perspective, governments of even small nations like Vietnam and Thailand (with much smaller GDP than India) spend more on their respective people's healthcare than what the Indian government spends on its citizens. China, with the largest world population, also spends more on healthcare than India (however, it must be noted that China's GDP is much higher than India).

Population aged 0-14 (in millions)	Population aged 15-64 (in millions)	Population aged 65 & above (in millions)
359	804	62

Table 2. India's population split-up for 2012 approximated based on World Bank data [1]

A population breakdown statistics shows that Indians between the age group of 15 and 64 are more than the total population of several other countries. A substantial number of people are aged 65 and above in India. With such a large population, there is demand for healthcare. Unfortunately, instead of targeting an increased spending

on public health, the government slashed approximately \$1 billion from its allocated healthcare budget of \$5 billion for the fiscal year 2014-15 due to fiscal strains [2]. With a traditionally very low investment on healthcare by the government, the onus is on private sector to expand and capitalize on the market.

Local market sentiments

Primary disease conditions prevalent in India are cardiovascular disorders, cancer, diabetes, followed by ophthalmology and gastroenterology related disorders. Awareness amongst the Indian public on disease management has never been stellar. Though public awareness programs have been shining a brighter light on cancer and cardiovascular disorders and promoting healthier lifestyles, other conditions such as obesity and diabetes are not treated with the level of criticality as it should be.

In 2000, India accounted for the maximum number of people suffering from diabetes – a staggering 31.7 million – and the number was projected to rise to 79.4 million by the year 2030 [3]. A recent International Diabetes Federation (IDF) report indicates that the projected number could be exceeded much before 2030, as a 2013 estimation showed the prevalence of the disease condition in 65.1 million Indians [4]. Rough estimates indicate a large prevalence of the disease in rural population and the typical causal attributes are:

- 1) Poor economy
- 2) Lack of infrastructure options for screening and preventive services
- 3) Lack of awareness on disease management options

Even people aware of treatment options opt for dietary modifications or lifestyle changes to hold the disease condition at bay rather than prescribing to drug or device treatment, especially when it comes to diseases that are perceived to be not life threatening immediately. In fact, a recent survey conducted by Abbott in collaboration with the Association of Physicians of India (API) shows that 90 per cent of people surveyed with uncontrolled diabetes believe that their blood sugar is under control, contradicting their actual state of health. 50% of respondents monitor their sugar levels only once in three months, while people with uncontrolled diabetes are recommended to have the sugar levels monitored at least twice a day. In addition to failing on monitoring blood sugar at regular intervals, 40% of respondents said that they adjust the dosage of their prescribed medications themselves to manage diabetes [5].

The Indian glucose monitoring device market may be dominated by a few key players such as Roche, J&J, Abbott etc. But there are several other startups that have failed to capture the diabetes management market in India despite offering products that were much more economical than the ones sold by foreign device manufacturers. One of the key learnings to note from such failed startups is that preventive care

or disease management is not taken up seriously by a large section of the Indian population. For critical life sustaining devices, with all other treatment options ruled out, people opt for best-in-market devices that fit within their purchasing power. For non-critical disease conditions or conditions that are not perceived to be immediately life threatening, reception to device-based treatment has been lukewarm. This conclusion is drawn not just with respect to diabetes, but chronic pain management treatment as well. Even though 14% of the Indian population is reported to be suffering from chronic pain according to a World Health Organization survey [6], there are very few pain treatment facilities and pain management related physicians, as opposed to over 3000+ physicians in the US [7].

Unmet clinical needs due to technology mismatch and existing economy

75% of India's total demand for medical devices is currently met by imports, with nearly 30% of it being supplied by United States alone [8]. In this scenario of high imports from a country which leads medical device innovation, there is a mismatch between the design of certain technologies being imported and realities of clinical conditions and healthcare infrastructure existing in India.





Phased-out legacy devices tend to get marketed and sold in developing countries including India. A device that is cutting-edge does not find a market due to lack of training options available to physicians or due to the high price tag associated with the device. Implanting a left ventricular assist device (LVAD) (an electromechanical circulatory device that is used to partially or completely replace the function of a failing heart) costs upward of \$100,000 [9] [10]. India has a huge market for such cardiac assist devices where a large population is affected by cardiovascular disorders. In the west, as devices evolve into the pediatric segment and miniaturization, older generation technology will still find

a market in India if offered at an affordable price. Essentially, device manufacturers need to understand the mismatch between technology and prevalence of disease conditions and existing economy, if they want to expand and capture market share in a developing country like India.

Healthcare providers

Just like in any other market, Indian healthcare providers play an influential role in the domestic medical device industry. In the last few years, corporate-style hospital chains have been permeating India's tier I and tier II cities. At the same time, independent hospitals have also

developed into centers of healthcare excellence and compete on the grounds of skilled physicians, quality of service offered and cost benefits to patients. A few examples are G Kuppuswamy Naidu Memorial Hospital (GKNM) in Coimbatore, Frontier Lifeline Hospital (founded by eminent cardiologist Dr. KM Cherian) in the suburbs of Chennai and P.S. Mission Hospital in Kochi which operate by charging patients who can afford treatment (usually middle class and above) while catering to a segment of the population that is economically challenged as well.

In addition to these hospitals providing treatment to patients in surrounding towns and villages, some of these serve as attractive destinations to foreign patients who look for affordable healthcare without compromising on the quality of treatment. Such hospitals present an opportunity to sell large volumes of medical devices on a fairly consistent basis.

It is imperative for device manufacturers to identify the right target patient population for their products, identify healthcare providers who have access to the target patient population, price their products strategically and establish and strengthen their alliance with the identified healthcare providers to maximize their revenue.

The heart valve market in India has been well capitalized by device manufacturers who have adopted the above strategy. Indian product - TTK Healthcare's Chitra heart valve - enjoys a good market share in the heart valve market that is inundated by global players like Medtronic, St. Jude Medical and Edwards. These foreign device manufacturers have strategically priced their products such that their target patient population is mutually exclusive. Medtronic's valves are priced attractive to the Indian middle class that prefers quality foreign products at an affordable price, while Edwards' devices are premium priced and target the affordable elite.

Regulatory environment

Medical devices in India are regulated by the Central Drugs Standard Control Organization (CDSCO) and follows the regulations laid forth in the Drugs and Cosmetics Rule (1940), though with a lot of ambiguity.

Historically, medical devices were classified as drugs and were subjected to the same rules that applied to drugs. After 2005, some devices such as disposable syringes, needles, stents (cardiac & drug-eluting), catheters, canulae, intra-ocular lenses, heart valves, orthopedic implants and internal prosthetic replacements were classified as 'notified medical devices' and were mandated to be registered and regulated. All other devices (other than intra-uterine devices – which are classified as drugs) fall under the category of non-notified medical devices for which registration is not required. However, amendments have been made in the recent past to address the lack of standardization across the devices portfolio and the list of notified devices has expanded now to cover over 160 devices.

Several recommendations have also been made to make the regulatory framework more stringent and covering aspects such as classifying medical devices along global guidelines and directives, setting up notified bodies to conduct quality audits of manufacturing facilities, adopting international quality management standards, conducting clinical trials and evaluation of medical devices as per Global Harmonization Task Force (GHTF) guidelines (as at present there is no document detailing the guidelines for conducting medical devices-related trials) and finally, adopting post-market surveillance of approved devices. Due to lack of a well-documented or a robust regulatory framework such as the FDA's, indigenous device manufacturers adopt international quality standards on their own as they progress on their maturity

curve. However, the level of adherence to such standards is questionable and there is a general lack of trust in the products manufactured in India.

Regulations not only affect the product development process or product quality, but also affect the economics of the industry. At present, the Indian tax codes are skewed in favor of device imports. Raw materials required to manufacture devices have a higher import duty than those for imported finished devices, thereby making imports of low-price foreign devices more financially viable than indigenous manufacturing. Furthermore, the government does not provide attractive incentives for setting up manufacturing units in India thereby making the country an import-driven market than a manufacturing hub.

These are regulatory-linked issues that are impediments to domestic device manufacturers, but are in favor of foreign device manufacturers who sell their products in the Indian market.

Reimbursement policies

State governments provide health insurance schemes that are geared towards helping poor people (who cannot otherwise afford treatment) benefit from free treatment in affiliate hospitals. A few good examples of state government funded insurance schemes are the Chief Minister's Comprehensive Health Insurance scheme by the Tamil Nadu government and the Rajiv Aarogyasri by the government of Andhra Pradesh.

Apart from state coverage, the central government also has schemes that benefit the poor. Some noteworthy health insurance schemes are Rashtiya Swasthiya Bima Yojana (RSBY), Employment State Insurance Scheme (ESIS), Central Government Health Scheme (CGHS), Aam Aadmi Bima Yojana (AABY), Janashree Bima Yojana (JBY) and Universal Health Insurance Scheme (UHIS).

In addition to all the above, private insurance companies provide coverage based on the sum insured. Despite such initiatives, it has been estimated that health insurance coverage is availed by less than 10% of the Indian population and that more than 80% of healthcare costs are paid for from out-of-pocket [1].

Device manufacturers must be aware of coverage limits and the demographics whilst pricing their products in order to capture the biggest market share possible. For mature medical products such as heart valves, stents etc., coverage has been determined and available for insurers. However, for evolving new products such as LVADs, total artificial heart etc., coverage has not been established thereby making these expensive products available only to the privileged few.

TN government insurance scheme	Coverage amount: Up to Rs. 1 lakh for certain procedures
	Eligibility: Family with annual income of less than Rs. 72,000
	Covers: 1,016 procedures, 113 follow-up procedures and 23 diagnostic procedures
AP government insurance scheme	Coverage amount: Up to Rs. 2 lakh for treatment of serious ailments including hospitalization and surgery
	Eligibility: Families below poverty line
	Covers: 938 treatments



Local success stories

Traditionally, the Indian medical device industry has operated on a model of frugal innovation with the objective of making products available to a wide patient population. Despite facing headwinds associated with the medical device industry in India, some indigenous companies have managed to navigate the hurdles and emerged successful. Discussed below are some success stories.

TTK Healthcare

TTK Group, started in 1928, operates across several industry segments, with TTK Healthcare focusing on medical devices, pharmaceuticals and consumer healthcare products. In 1991, TTK commercialized the technology of building mechanical heart valves indigenously from Sree Chitra

Tirunal Institute for Medical Sciences and Technology (a speciality hospital and medical research centre in Trivandrum). Marketed as TTK Chitra heart valve, it is the most economical heart valve in the market, while mechanical valves of similar features are sold for at least three times more. The valve is now exported to countries such as Thailand, Myanmar and Kenya. Apart from heart valves, the company also built India's only FDA approved knee surgical implant. Other than medical devices, several prominent products have come out of TTK Healthcare's manufacturing units over the years, some of which are Woodward's gripe water, Skore contraceptives, Eva deodorants and immunomodulators for farm animals. The company had an annual turnover of Rs. 382 crore for FY 2012-13 [11].

Appasamy Associates

The company started operations in 1978 building low cost ophthalmic devices for the Indian market. With an operating model aimed at low profit margin and high sales, the company delivered products that were one-third the price of an imported device. The company introduced world's first non-electric vitrectomy device (a device that is used to surgically remove some or all of the vitreous humor from the eye) in 1979 followed by a stream of ophthalmology devices subsequently. Foreseeing evolving trends in the market, the company delved into developing intraocular lens that were made available to the public for Rs. 200 (~ \$3) in 1988 [12]. The company expanded its product portfolio, set right its quality systems, made itself compliant with global standards, and now currently operates in India and Africa,

employs more than 1000 people and its revenue is now in the range of Rs. 100-500 crore [13].

Trivitron Healthcare

Trivitron started in 1997 with the objective of being the 'single point of technology contact' from which healthcare providers can source all technology needs that fall within the realm of in vitro diagnostics (lab diagnostics), in vivo diagnostics (imaging), medical devices (equipment and non-invasive), dental, ophthalmology, critical care, operating room and healthcare IT. It is now India's largest wholesale distributor and after-sales support provider of medical equipment and devices. The company differentiates itself by providing cost effective solutions that are competitive, along with superior post-sales service, both of which are favored by hospitals that procure the services of Trivitron. Apart from India, the company has now expanded its operations to Middle East, South East Asia and Africa and had a revenue of Rs. 400 crore in FY11 with anticipated revenue of Rs. 500 crore the following year [14]. The company had acquired a Finnish manufacturing company in 2012 and also attracted investments from private equity firms, thereby setting it on a path of robust growth.

Aurolab – division of Aravind Eye Care

With a lot of critical life sustaining devices even today still following a very labor intensive manufacturing process,

Aurolab managed to design a system that supported large volume production of intraocular lenses using a system that was heavily standardized with minimal dependence on discretionary elements in the process. Where they really excelled was not with the development of the product alone, but with the development of an entire ecosystem surrounding the product that catered to millions of people. Apart from a factory to build the lens, the following were also setup – training centers, ophthalmic research centers, an international eye bank and an eye camp model to take their products to rural locations where people were educated, diagnosed and treated for ophthalmic disease conditions. Along with innovations in their daily operations, the system works on a low cost - high volume model, where a proportion of patients pay the premium for services while economically challenged are treated for free. What entices affordable patients is not only the price, but the quality of service as well. Thus, quality is not compromised in the name of business model, making Aurolab an indigenous success story.

How these companies succeeded by overcoming inherent market challenges

TTK Healthcare succeeded by strategically pricing its product and establishing strong partnerships with healthcare providers. Tie-ups with insurance schemes also proved beneficial for TTK Healthcare. Being the cheapest product in the market,

demand from large number of the economically downtrodden, drove sales. TTK also did not play catch-up with the western market where the heart valve technology had evolved into tissue-based products and transcatheter segment. TTK concentrated on making only one product – the mechanical heart valve, backed the product up with technical publications that clearly demonstrated that its performance was comparable with foreign products and focused on increasing sales with that one product.

Appasamy Associates understood that the market was not completely tapped into due to the existing economy and low purchasing power of the population. Thus, the company succeeded in permeating the market better by creating indigenous products and banking on the low cost - high volume model.

Trivitron clearly identified healthcare providers' need from an operations perspective. Its success lay in its combined offering of solutions (that were in demand), along with best-in-class services.

Aurolab succeeded not just because it understood the existing economy, but because it was able to create value added services that were actually beneficial to patients.



Recommendations to capitalize on the Indian medical device market

Despite India's unique market dynamics, local sentiments and challenges, there are strategies that device manufacturers can utilize to capture and maximize on the market share.



Fig 2. Recommended steps to capitalize on the Indian market



Develop partnerships with indigenous technology firms

Partner with indigenous technology firms to conduct customized market research and analysis, identify best distribution channels, establish sales channels and lay out roadmaps for long term growth. Indigenous technology firms provide the necessary talent to understand local regulatory expectations, evaluate tax duties and implications of import, investigate Indian payment practices unique to local market and also help select the right sales channel partners. One of the best known collaborations of a western company with an indigenous technology firm is Wipro GE Medical Systems.

For companies that already have a presence in India, growth strategies such as revolutionizing sales force or portfolio expansion can be developed as per company's goals and vision.

Adopt technology and climb the maturity curve in marketing

In contrast to the western market, advertising the benefits of medical devices or drugs through print, visual or social media is not permitted in India. Thus, success of the medical device industry's B2B model depends to a great extent on the sales force on the ground. Even to date, sales happens through traditional methods of hospital visits by sales representatives, and at times by providing products to be used by clinicians for an extended period of time without paying for them upfront. With new marketing channels evolving, digital marketing platforms such as tablets should be adopted that will essentially help sales force deliver personalized messages, segment customers based on loyalty on the go, deliver content based on customer preference and also increase customer interaction experience, thereby furthering chances of revenue growth.

Add value to stakeholders

Contrary to popular consumer trends in India where lower cost is preferred over quality, owing to the criticality of life sustaining medical devices, people prefer to pay premium price for quality medical devices. To further capitalize on such a market with economic potential, it is imperative for companies to extend the same value-add, that is being adapted in the western market, in India as well.

In the west, device manufacturers are moving away from being pure play manufacturing units into value-added firms in order to further position themselves as brands with recall. Off late, Medtronic has embarked on a journey to showcase to its stakeholders clinical and more importantly, economic value that their products bring in. Clinical value of medical products is fairly straightforward – a patient's quality of life is alleviated due to the medical product that is used.

However, demonstrating economic value, especially when the associated healthcare costs surrounding the device skyrockets, is a bit challenging. To address such a challenge, Medtronic has started several programs in parallel, one of which is a two-year pilot program in partnership with Aetna (a health insurance company) wherein 300-diabetic patients covered by Aetna are put on Medtronic's insulin pump therapy. The objective of this pilot program is to demonstrate that the insulin pump therapy is more effective in managing the expensive diabetic disease condition than daily insulin injections.

Medtronic also recently partnered with the government of Lombardy, Italy, to tap into the patient outcome data of the population that had used Medtronic's products. The objective was to understand the specific impact of therapies offered by Medtronic by evaluating the quality of treatment, outcome of treatment and also the overall

cost involved. Such a partnership will help generate specific economic value propositions for each therapy long after the surgery is completed.

There is truly a paradigm shift happening now where companies are looking for ways to add value to stakeholders beyond just selling their products. To capture and better capitalize on the Indian market, it is recommended that device manufacturers demonstrate a similar value-add not just in the west, but in India as well.

Push for regulatory and tax code changes

This recommendation applies only to Indian medical device manufacturers.

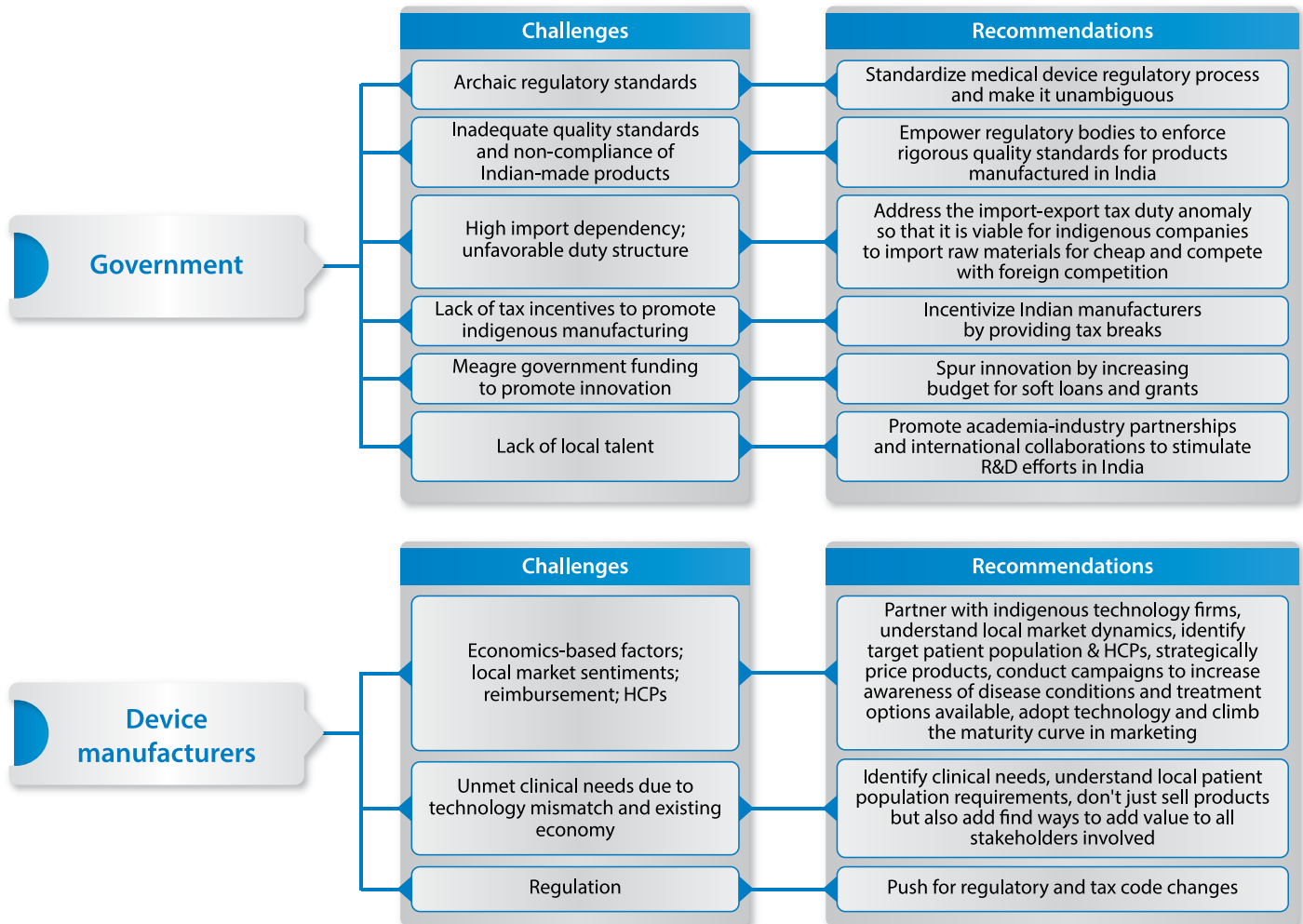
Apart from pushing to create regulations specific to medical devices, Indian companies should also lobby to fix tax codes that are not in favor of indigenous manufacturing. A lot of western companies have setup wholly-owned subsidiaries in India with warehouses for domestic distribution of their products, than setting up manufacturing units due to this particular skewed duty structure.

Furthermore, with no tax breaks or incentives to set up manufacturing units in India, opening up of the medical devices sector to a 100% Foreign Direct Investment (FDI), as initiated by the current government, may not yield the desired outcome.

Thus, it is recommended that the skewed duty structure be fixed and attractive tax incentives be provided for setting up indigenous manufacturing units, and that Indian companies push for these changes if they want to compete in the market with foreign competition.

Summary of recommendations for the government and device manufacturers to address challenges existing in the Indian medical device market.

Summary of recommendations for the government and device manufacturers to address challenges existing in the Indian medical device market



Conclusion

Market dynamics specific to India, local sentiments, headwinds and opportunities have been presented in this whitepaper along with a set of recommendations. The Indian medical device market, with all its potential, can be fully maximized when the government and device manufacturers implement the prescribed recommendations, which will then open up the market to be a multi-billion dollar opportunity, much greater than the mere \$3+ billion that it is now.



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About the Author



Dinesh Peter is a Consultant with the Life Sciences & Services practice of Infosys' Consulting Services. He has 5+ years of experience in new product development, process re-engineering, quality compliance and digital marketing transformation across the life sciences industry. He can be reached at dinesh_peter@infosys.com.

For more information, contact askus@infosys.com



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