

Opportunity for Made in India medical devices in global markets: Role of Quality

Balram Sankaran and Dr Shiyas C R
Cochin University College of Engineering Kuttanad,
CUSAT, Kerala 688504
Email: balrams@gmail.com

Abstract - Medical Device industry consist of a large number of small and medium enterprises that produce a wide variety of heterogeneous products known as medical devices. Medical devices play an important role in healthcare delivery and has a growing global demand. The domestic manufacturers of medical devices in India have a good opportunity to supply to the increasing demand in expanding global market with made in India medical devices. The quality of medical devices made in India will determine the success of Indian medical device manufacturers to become a global player.

Keywords - medical device; quality; medical device industry

INTRODUCTION:

The current pandemic has brought out the significant role played by medical devices in healthcare delivery in the modern world. Even though modern healthcare system is dependent on hundreds of products coming under the category of medical devices, these products are not known much to people at large and remain confined to the professionals within the healthcare system. These products at times significantly impact the healthcare costs as well. The products are of diverse nature, utilising different technologies from different disciplines, with varying role in prevention, diagnosis or therapeutic use and interaction with the patients. These products are made in large numbers by a thriving industry, known as medical device industry, in different parts of the world, employing a large number of people and contributing to the economy. Yet just like the medical devices, the medical device industry is also not in the limelight unlike

other industry segments such as automobile or consumer electronics etc in India. The medical device industry in India is still in a nascent stage, yet to make use of the emerging opportunity. This paper attempts to analyse the factors that herald the growing opportunity for made in India medical devices to capture a growing demand world wide and the role of quality in facilitating the Indian medical device domestic industry manufactures to capture the global market.

Medical Devices and Industry scenario in India

Healthcare industry is generally considered as a recession free industry and medical products are always in demand. The market growth rate of medical products including medical devices is generally very positive and encouraging for the manufacturers. The market is always expanding irrespective of the cycles of growth and slump in other industry segments. Access to good quality, affordable and appropriate medic products is essential for good health care delivery system. There are a large number of products, from seemingly simple items such as a bandage to ubiquitous products such as a stethoscope or a thermometer to highly complex equipment like an X ray or CT imaging device that are considered broadly as a medical device. There are products like a syringe that temporarily go inside the body to implants like knee joint that are placed permanently inside the body. All these hundreds of myriad products that interact with a patient for a short/long duration in an invasive/non-invasive mode and which have different

roles such as for prevention, diagnosis or treatment, are broadly termed as a medical device. In a modern world, it would be impossible to imagine any healthcare delivery without the use of one or other kind of medical device. It is estimated that there are over a million different kinds of medical devices in the global market, which are divided into into some 7000 generic devices groups. Medical devices also include reagents for in vitro diagnosis and software used in medical application. For the sake of regulation purposes, the vast number of medical devices are classified based on the risks associated with the use of such devices.

Medical devices are made by manufacturers which belong to the medical device industry. With the exception of some large multinational corporations, globally, medical devices are made by small and medium scale enterprises. The worldwide medical device market was estimated to be US\$ 455.34 billion in 2021 and is estimated to be growing at the rate of 5% [1]. The major market share of the global market is addressed by medical device manufacturers located in the USA. The Indian medical device market is estimated to be worth US\$ 10 Billion in 2021. Most of the demand for the medical devices in India is said to be through import. Medical devices worth about US\$ 2.1 Billion was exported from India in 2019 [2]

There is a growing domestic medical device manufacturing company base in India. These are mainly small and medium size enterprises and present in some prominent informal clusters in different parts of the country. Most of Indian domestic manufacturers are engaged in manufacturing of low value low technology disposables, medical electronics based devices etc. There are some areas in which India is already exporting in a big way and this includes Intra ocular lenses and coronary stents Now we are witnessing a trend of start ups coming

with innovative devices trying to address unmet needs. These start ups are employing new and emerging technologies like artificial intelligence, machine learning etc and using Industry 4.0 technologies. India is suited for medical device innovation and manufacturing. India offers natural advantages such as lower manufacturing costs and availability of skilled manpower. Specifically for medical device manufacturing, there is a need to implement standard operating practices (SOPs) and personal hygiene is essential for implementing a good manufacturing practice environment, for which it is important that the people are educated and able to understand the importance of these factors and not to cut corners. In spite of these positive factors, in India medical device manufacturing has been a low key affair in the past.

However, in the recent times, due to several initiatives, there is a push towards increasing domestic or make in India for medical devices. New medical device parks are being announced in several regions of the country. These exclusive parks will provide the right ecosystem for medical device manufacturing and will have tie up scientific and technological institutions, incubators, testing houses, certification bodies etc. The regulatory system in India was not adequate and was often cited as the reason for lack of domestic manufacturers to export or capture global markets. However, the regulatory system for medical devices in India is set to change for better with the publication of medical devices rules 2017 by Central Drugs Standards Control Organisation (CDSCO). The new regulatory system will make it necessary for the Indian medical device manufacturers to adopt quality management systems for their operations. For gaining market acceptance, medical device manufacturers must adhere to safety standards and performance benchmarks in their products. These are to be established through

rigorous testing and validation processes followed by a regulatory approval.

Role of Quality in medical device manufacturing industry

Quality is not an accident. It comes by design and willingness of top management to implement a quality management system in the company. Indian manufacturers of medical devices need to understand the various benefits of implementing quality management system and not just as a pre requisite to meet the regulatory requirements. Improving quality can bring costs down significantly and will help in more customer acquisition and market expansion. The need for quality in the design, manufacture, and distribution of medical devices is today much more relevant than ever before for the medical device manufacturers in India. Good quality practices in manufacturing operations alone can save revenue losses due to defects and rejections. Manufacturers may adopt several practices that lead to good quality outcomes in their products. These include training and implementation of right quality tools that are widely applied in other manufacturing enterprises such as automobile or consumer electronics sectors. Application of proper quality tools and techniques in manufacturing will lead to reduced manufacturing costs and reduced lead times. A robust quality culture and practice across the organisation can transform the quality outcomes. Quality control tools are building blocks for any quality improvement project and with proper methods to collect and analyse data, process improvements can be achieved. Selection of the right set of quality control tools such as pareto analysis, fish bone diagram etc are simple, easy to implement yet powerful in bring out a quality change. Reducing variation by capturing and analysing data using process control charts can be effective in reducing rework and wastages. The cost of ensuring good quality is only a fraction of the loss due to

poor quality. In the case of medical devices, poor quality may be at times life threatening and may have wider implications such as regulatory actions such as recalls, shutting down of facility etc. These have much more implications than direct costs and indirectly affect the image and brand.

Medical device manufacturers can adopt the ISO standards which serve as valuable guides to achieving quality goals of an organisation and product. ISO 13485 is a standard that specifies the quality management system specifically for manufacturers of medical devices. This standard sets out the requirements that a manufacturer of medical devices must adhere to in order to demonstrate that it is capable of producing medical devices that meet both customer requirements and regulatory requirements where applicable. This standard covers the entire lifecycle of a medical device right from design stage to production and manufacturing, logistics operations, installation and after sales servicing. This is a standard that can be applied by all types of manufacturers of medical devices irrespective of the size or nature of product. This standard is a specific standard applicable for medical device manufacturers and emanates from the generic ISO 9000 quality management system standard that can be applied across all industry segments. Like in ISO 9000, this standard also is process oriented and gives thrust on instilling a process-based quality management system

Conclusion

Indian manufacturers of medical devices have a growth led market demand, cost competitiveness, skilled manpower and an emerging world class infrastructure and regulatory regime. Therefore, now it is an opportune time for Indian manufacturers of medical devices to focus on quality. This can open up to the opportunity to get a share of the growing global market for medical devices. The healthcare industry has been witnessing unprecedented attention due to pandemic and has expanded the scope of the industry. There is a great need and opportunity to cater to unmet clinical needs of the world with good quality affordable products. Medical device companies that embrace the quality and emerging demand will be able to grab the emerging opportunities. It is an opportune time for Indian companies to not only meet the customer expectation, but to exceed them. By giving quality its due in medical device manufacturing, Indian companies are well poised to become a supplier to the world thereby creating huge economic benefits to the country

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