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Research Article

EFFECTIVE IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM AND REGULATORY STANDARDS FOR MEDICAL DEVICE PRODUCTS

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ABSTRACT

The implementation of an effective quality management system has always been considered a principal method for a manufacturer to maintain and improve medical device product and quality of service. Globally many regulatory authorities incorporate quality management system as one of the mandatory requirements for the regulatory control of high-risk medical devices. The present study describes about the current practice of medical device industry in India. The regulatory implementation of GMP requirement in medical devices has already taken and implemented to assist small and medium-sized enterprises in compliance with the regulatory requirement. Present trend is to promote medical device manufacturing to the current regulatory requirement changes. The Indian Government is giving subsidies to one who wants to manufacture or expand their business through Make in India program.Transition in the production and the advanced technologies involved in the medical device industry provides the greater scope to the competent authorities that India is one of the medical device manufacturing sector around the world with a safe, quality product which meant for intended purpose which gives best performance to satisfy the customers around the world by implementing QMS as per the recent regulatory changes.

INTRODUCTION

QMS is one of the strategies to sustain, maintain and to improve quality of the product and service. Along with other regulatory requirements India around the globe India also recently revised its guidelines to ensure the safety and effectiveness of medical devices. Imports of medical devices constitute over 75% of the current medical devices market. Thus currently India is addressing its demands through Make in India Program to supply medical devices in India.

The Indian medical device industry is fast growing with academic research, venture capital firms, government funding, and several local and MNCs startups which are developing medical devices specifically for the Indian market. The faster growth involves transformation across the industry to improve growth by value, and gets an opportunity to sustain its business through Make in India drive.

In 2017, the Medical Device Rules, issued by the Ministry's Central Drugs Standard Control Organization (CDSCO) (7). This gives a quality system requirement to the manufacturing industry to ensure medical devices are manufactured as per the medical device rules with continuous improvement strategy. The QMS regulation also requires establishment of documentation, form, procedures and records for any investigation related to quality and patient safety in relation to the medical devices concerned (8).

The international standard, ISO 13485:2016, medical devices—quality management systems—requirements for regulatory purposes, as the title suggested specifies quality management requirements for the medical device sector for regulatory purposes.

India is growing rapidly as a destination for medical device manufacturing. Costs to manufacture in India are generally significantly less due to recent change in the regulations and policies. We have to strengthen the Quality Management System by using current policy changes.India's GMP standards for medical devices and drugs are covered in Schedule M and Schedule M III of the Drugs and Cosmetics Act (DCA). It mainly describes the quality assurance, quality audit, and quality control system requirements for medical devices and pharmaceuticals. It also describes the requirements for the factory premises, materials, plant, and equipment as per WHO. Indian GMP regulations are more aligned with ISO 13485.

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Standardizing quality requirements will help manufacturers in India register their medical devices more effectively (9).

Depending on the type of medical device, the Drug Controller General of India (DCGI) and the State FDA will approve or determine the medical device licensing process. The application for a manufacturing license may include manufacturing processes, product details, and information about the staff. In addition, there are many state and local level licenses that are needed to manufacture a medical device. Therefore, understanding the regulations of a particular Indian State is important when deciding on a manufacturing site location.

Currently Indian Medical device Industry depends on import and domestic manufacturing units in India and is highly fragmented. Due to current regulatory and policy changes in India, the Indian medical device industry is expected to have a big transition/consolidation. There are five Medical device clusters across India. The availability of skilled and unskilled labors is based on the state level policies. North Indian medical device manufacturers are concentrated on low end consumable based on low labor cost and policy incentives. Whereas South India is manufacturing high end devices with their highly skilled labors. The Indian Govt. have improved favorable policy and regulations and attracted number of local medical device manufacturers and also several MNCs to manufacture medical devices in India due to advances in technology and market demand. Some manufacturers enjoy a constant growth of business after regulation enforcement such as Trivitron, Sutures India and PerfintHealthcare.

QMS describes the whole internal and external issues of the organization. Since ISO 9001:2015 explains the requirement of GMP and management documentation as per the service of the Industry. For QMS in medical devices most of the clauses aligns with ISO 9001:2015 clause. Thus it is facile for medical device industry can incorporate all essential requirements in the QMS since ISO 13485:2016 resembles ISO 9001:2015.

The objectives of QMS for quality assurance of products are achieved by implementing and maintaining the documentation. Document (includes record) system is important constituent part of QMS. In this paper we describe the important issues and relative requirements of GMP on the establishment and management of documentation within quality management system (QMS) of medical device organization with the aim to improve and build QMS in organization to implement GMP.

METHODS

The work was done based on onsite management of QMS in medical device manufacturing company and survey. Some of the current driving forces in the medical device industry is presented in the diagram (Fig. 1) (6).

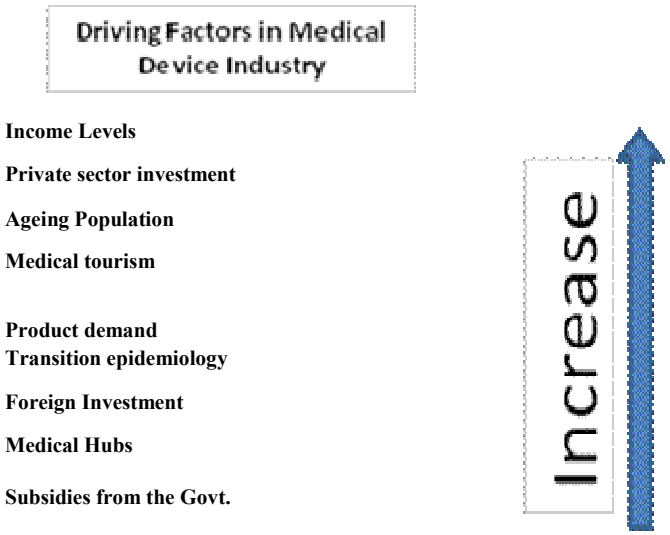

Figure 1 Driving forces in medical device industry (see ref. 6).

The recent statistical survey of India medical device market was compared with other important global medical device markets in the Table 1 (ref. 11). The Indian medical device market is growing steadily. It was valued at US$3.5 billion in 2015 and isexpected to approximately US $4.8 billion by 2019. As India's economic condition, quality of healthcare evolve, leads to increase in medical device market as a promising opportunity for foreign manufacturers.

Table 1 Survey of India medical device market (ref. 11)

	India	USA	China
Population	1,251,695,584	321,368,864	1,367,485,388
Size of medical device market (USD)	$3.5 billion (USD)	$147.7 billion (USD)	$8.7 billion (USD)
Number of hospital beds	0.7 per 1000 people	2.9 per 1000 people	3.8 per 1000 people
Expenditures on healthcare	Government: 30% Private: 70%	Government: 48% Private: 52%	Government: 56% Private: 44%

RESULTS & DISCUSSION

Documentation

QMS was implemented and ensured the following documentation in place:

1. A description of the legal status of organization.
2. Documentation showing the responsibilities and reporting structure for the flow of processes and personnel. Safety representative to take account of information on medical devices in use as per existing national law and regulations.
3. Records to demonstrate the conclusions of performance evaluation of the medical device and manufacturer's compliance with the requirements of the relevant standard. For performance evaluation the organization evaluated the post marketing surveillance and the outcome have shown that there is no adverse events where as recent past evaluation shown that very few complaints regarding the performance of the products (Fig.2)

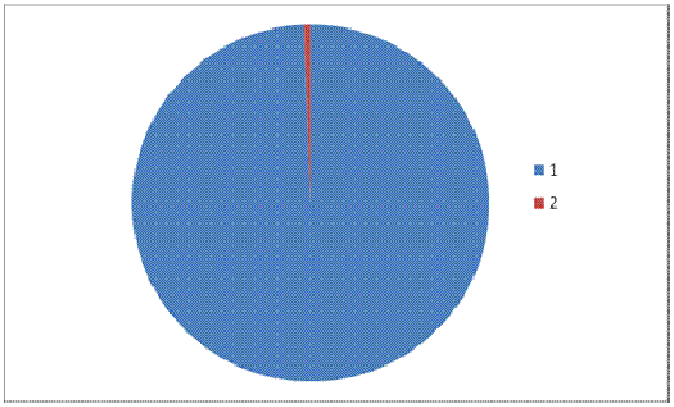

Figure 2 Evaluation of complaints regarding the performance of the products 1. Performance Evaluation of the Products used2. No of complaints communicated.

4. Procedures for manufacturer's compliance with the requirements of the standards in terms of policy, objectives, resources like controlled work environment, manpower, documentation requirements, medical device records, product design and development, planning, development input, review, verification, validation, design transfer, output, design controls, Purchasing process, specification, Identification and traceability, verification of the product, performance evaluation, data analysis, complaint handling, feedback, internal audit and management review.
5. Procedures relating to the issue, any changes, rejection, and withdrawal related to the medical device. These procedures shall include a requirement to inform the regulatory authority incase of any adverse event, and how to distinguish the recalled product with the conformed product.
6. Details of obligations regarding communications with in the organization, and regulatory authorities.
7. Procedures for assessing and monitoring the competence of subcontractors, in case of any extend of control used for evaluating the same.
8. Details of record keeping facilities including means to ensure security and confidentiality.

Implementation Guidelines

Companies seeking initial ISO 13485 certification will be required to follow and comply documentation to meet the new requirements of 2016. If any of the process is not performed properly it can have great impact on compliance and product performance. Thus a risk based approach is always helpful in planning and manufacturing medical devices. This standard exists to ensure that the requirements of sterilization regulations are followed as per ISO 11135, 11137, 11138. It also requires sterilization and sterile barrier validation prior to any implementation of routine production processing (10).

CONCLUSION

Current growth of Indian medical device industry after recent changes in the regulation has shown a great consolidation. International competiveness of Indian medical device industry is enhanced by implementing and maintaining QMS in the organization. It will attract the healthcare customers around the world. Global Policy makers need to understand and evaluate the impact of regulatory requirements on the local small-to-medium-sized manufacturers and implement a harmonized regulatory system with care to mitigate the impact, thereby ensuring the success of the implementation of their policy.

The present study suggested that the implementation of QMS regulation facilitates the quality transformation of local medical device industry. The standard set for strengthening the organization competiveness in both domestic and global markets by improving quality system and increasing human resource. The Indian medical device industry success can be contributed further from global market growth, technology innovation, increased financial investment, educated human resources, and governmental initiatives.

Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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