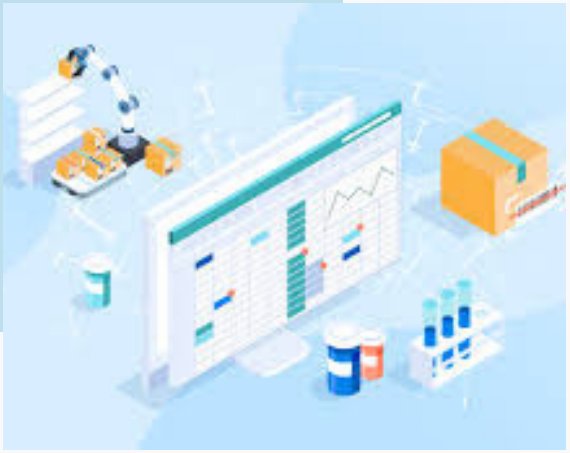

FICCI CERTIFIED TRAINING ON EFFECTIVE IMPLEMENTATION AND INTERNAL AUDIT OF ISO/IEC 13485:2016 MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM

2023

About

India is one of the top 20 nations in the world for the medical devices market. However almost 70% of the devices are imported and hardly 30% are indigenous products. The basic reason being lack of trust! The need for certification of medical devices is increasingly becoming a necessity owing to a large part of diagnostics today relies on medical devices. Having the medical device certified for safety and performance is of utmost importance to ensure a certain degree of reliability in understanding the disease. World over there are regulations which have made many medical devices mandatory. In India all medical devices would be under licensing w.e.f oct 2023 by CDSCO to enhance safety /performance & global competitiveness. BIS also has brought certain medical devices under mandatory certification scheme.

A common factor to certification of all medical devices is the compliance to ISO 13485!

24 - 26 July 2023

Course Registration and Details:
Time: 9:30 AM - 05:30 PM
Nature: Onsite
Venue: FICCI Office, New Delhi
Participation Fee: Rs 20,000 + GST (18%)
Contact: Mr M Tariq Inam
M: +91 9910934929
E: tariq.inam@ficci.comlfqf@ficci.com

ABOUT FQF

FQF -the training and consulting wing for FICCI is focused on providing value added services to Industry in the Process, People and Sustainability domain. It is pioneering in introducing contemporary tools and techniques to Indian Industry and providing learning and implementation solutions ranging from accredited courses on various management system standards, Business Excellence, Project Management, Risk Management, Resource Efficiency, Circular Economy and people domain – providing people management processes, capacity building and DEI (diversity , Equity and Inclusion) interventions to corporates in India and abroad.

The division is focused on enhancing the quality quotient of client and partner organization and making them CRISP i.e. Competitive, Responsible, Innovative, Sustainable and Profitable through the means of training, research, knowledge work in thought leadership, benchmarking and advisory.

ISO 13485:2016 Medical Devices

COURSE OBJECTIVE

The aim of the course is:

- To provide comprehensive understanding of requirements of ISO 13485:2016.
- Build capability to drive implementation of ISO 13485 in organization leading to certification
- Provide guidance on classification and schedule IV and V of MDR2017 to enable regulatory compliance.
- Conduct an effective gap analysis and internal audit of Medical Devices

COURSE ATTENDEE

- Get CDSCO approval for any of your products
- Work in the field of Quality assurance, servicing or Installation of medical devices or as Design Engineer for Medical Devices
- Build a robust management system to enhance credibility of your product
- Meet regulatory requirements and customer expectations on consistent basis
- Export to countries looking for CE and other Global conformity for your product
- Increase efficiency, cut cost and monitor supply chain performance
- Demonstrate that you produce safer and effective medical devices

ABOUT OUR FACULTY

Our Lead faculty of this course Mr. M. G. Satyendra has more than 40 years of experience in the field of National & International Compliance. Served as Director Bureau of Indian standards (BIS), CSA International, Intertek, etc. Trainer for ISO/IEC 17025, 17020, 9001, and 13485. Past Assessor for NABL, Past Chairman for Quality Cell IEEMA and Trainer for Global Conformity for IMTMA, IEEMA Mentor for Medical Device Start ups, IIT Kanpur.

METHODOLOGY

A judicious mix of classroom presentations, exercises, case studies and hands on practice will be used. Participants will be encouraged to relate the learning to live situations.

CERTIFICATION

Participants who successfully complete the continuous assessment during the course and also the written examination conducted on final day of the course will be issued a certificate by FICCI