
# FICCI CERTIFIED TRAINING ON INDIAN AND EUROPEAN MEDICAL DEVICES REGULATIONS - I MDR & EU MDR

2023

## About

Medical devices are crucial tools that help healthcare professionals diagnose, treat, and prevent illnesses. However, the use of medical devices can pose risks to patients if they are not regulated effectively. The regulatory frameworks for medical devices in India and Europe aim to ensure that these devices are safe, effective, and of good quality. In India, medical devices are regulated by the Central Drugs Standard Control Organization (CDSCO), which oversees the import, manufacture, and sale of medical devices. In Europe, medical devices are regulated by the European Union (EU) through the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR).

Understanding the differences and similarities between these regulatory frameworks is essential for manufacturers, healthcare providers, and patients who rely on medical devices.

## 27 - 28 July 2023

Course Registration and Details:
Time: 9:30 AM - 05:30 PM
Nature: Onsite
Venue: FICCI Office, New Delhi
Participation Fee: Rs 12,499 + GST (18%)
Contact: Mr M Tariq Inam
M: +91 9910934929
E: tariq.inam@ficci.com|fqf@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.


# COURSE OBJECTIVE

The aim of the course is:

- To provide comprehensive understanding of requirements of Indian and European Medical Devices Regulations.
- Build capability to drive implementation of I-MDR in organization leading to certification
- Provide guidance on classification and schedule IV and V of MDR2017 to enable regulatory compliance.

# COURSE CONTENT

- TRAINER AND PARTICIPANTS INTRODUCTION
- OVERVIEW OF IMDR AND DEFINITIONS
- CHAPTER II CLASSIFICATION ; CHAPTER III AUTHORITIES, OFFICERS, BODIES
- CLAUSE IIIA & IIIB, REGISTRATION PROCESS
- CHAPTER IV MANUFACTURE ,
- CHAPTER V IMPORT, CHAPTER VI LABELLING CHAPTER V IMPORT, CHAPTER VI LABELLING
- CHAPTER VII CLINICAL INVESTIGATION OF MEDICAL DEVICE
- CHAPTERS VII TO X IMPORT NEW DEVICE, DUTIES OF OFFICERS, NB. LAB REGISTRATION
- SCHEDULE I,II &III CLASSIFICATION, FEES, NB REGISTRATION
- SCHEDULE IV DOCS REQUIRED FOR REGISTRATION
- SCHEDULE V -QMS
- SCHEDULE VI, VII AN VIII
- OVER VIEW OF EU MDR , THE KEY CHANGES
- EXERCISE RISK IDENTIFICATION AND MITIGATION
- EUROPEAN METHOD OF DEVICE CLASSIFICATIONS
- REQUIREMENTS REGARDING DESIGN AND MFR , DECL OF CONFORMITY
- CONFORMITY ASSESSMENT METHODS UNDER EU MDR
- MIN REQUIREMENTS IN THE CERTIFICATE. Q&A SESSION

# 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