Effective Implementation of ISO 13485:2016
Medical Devices – Quality Management System

Organized by

FICCI QUALITY FORUM

Mar 3 – 6, 2020

Hyderabad

1. Introduction

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 CDSCO has regulated many standards for compliance. Certain medical devices have been notified by CDSCO for registration to enhance global competitiveness and business growth. BIS also has brought certain medical devices under mandatory certification/registration scheme.

A common factor to certification of all medical devices is the compliance to ISO13485!

Almost all CDSCO approvals require compliance to ISO 13485 and this is also required by the Medical device regulations 2017 of the Government of India

This programme of FICCI is intended to provide comprehensive training on the 13485 standards along with auditing principles to enable the participants to conduct Internal auditing

2. Course Objectives

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 of medical devices as per MDR.

8. You should attend this course if you want to:

a. Get CDSCO approval for any of your products

b. Work in the field of Quality assurance, servicing or Installation of medical devices or as Design Engineer for Medical Devices

c. Build a robust management system to enhance credibility of your product

d. Meet regulatory requirements and customer expectations on consistent basis

e. Export to countries looking for CE and other Global conformity for your product

f. Increase efficiency, cut cost and monitor supply chain performance

g. Demonstrate that you produce safer and effective medical devices

9. Course Material

Course kit comprising detailed course material and International Standard ISO 13485:2016 is provided to each participant.

10.Methodology & Certification

A judicious mix of classroom presentations, exercises, group discussion, case studies and hands-on practice will be used. Participants will be encouraged to relate the learning to live situations. Participants who successfully complete the continuous assessment during the course and also the written examination conducted on last day of the course will be issued a certificate by FICCI.

11. Course Schedule & Registration Procedure

Date: Mar 3 – 6, 2020

Timing: 09:30 hrs – 17:30 hrs

Nature: Non residential

Venue: Hyderabad

Participation Fee: Rs. 27,850/- plus GST @ 18% i.e. total of Rs. 32,863/- (Includes cost of training, course kit, lunch, tea etc.)

Registration: Send registration form along with Cheque/DD in favour of "FICCI Quality Forum". The seats are limited to 20 and registration will be done on first come first serve basis

For further details, & to reserve your seat, please contact:

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7. About our Lead Faculty

Our Lead faculty of this course **M.G Sathyendra** is a Consultant with 39 years' experience of working in product certification, testing, corporate training and management consulting. He was erstwhile Director in Bureau of Indian standards, Head Indian operations of CSA International (Canadian standards body), Head for south and west of Intertek India. He has been Technical assessor for NABL and presently assessor for NABCB for witness audits of ISO 13485. He was also handling UL inspections in India for 16 years.

He has undergone training on 13485 by SGS UK and recently after the revision, by Pacific accreditation co-operation and Standards Malaysia.

Executed more than three hundred training/consulting assignments to various leading companies and laboratories in India; He was also the past chairman of quality cell of IEEMA .and Business excellence assessor for SME's

Associated with FICCI Quality Forum (FQF) as Consultant for management systems training and advisory services on ISO/IEC 17025 and others including ISO 13485. He is an engineering graduate from University of Mysore

8. About FICCI Quality Forum

FICCI Quality Forum (FQF) is the specialized training and consultancy division for Federation of Indian Chambers of Commerce and Industry (FICCI) established in 1992 to sharpen the competitive edge of Indian Industry.

FQF provides value added services to Industry in **Process, People** and **Planet** domain through capacity building programs, advisory services, research and work in thought leadership space. It is focused on enhancing the quality quotient of client and partner organization and making them sustainable, competitive and responsible.

FQF has collaboration arrangements with Intertek India for providing IRCA, UK approved Auditor/Lead Auditor training courses on ISO 9001 Quality Management System (QMS), ISO 14001 Environment Management System (EMS), ISO 22000 Food Safety Management System (FSMS), Occupational Health and Safety Management System 45001, ISO 50001 Energy Management System (EnMS), ISO 27001 Information System Management System (ISMS) etc. and also provide trainings on different Behavioural and skill based topics to Industry at large through pool of highly competent & experienced trainers .

In addition, we also provide training on Six Sigma Green and Black belt certification, and Project Management, Risk Management etc. We also provide consultancy support on effective implementation of above management systems including Laboratory Management System (LMS) leading to certification/accreditation.

9. Course Content **1. Introduction** 1.1. Scope of the standard. key definitions **2. General requirements** **2.1** Controlling documents and records, medical device file contents **3. Management requirements and resource management** 3.1 Customer focus 3.2 Quality Policy 3.3 Planning 3.4 Responsibilities and authorities 3.5 Management reviews-content **4. Product realization, Measurement Analysis and improvement auditing** 4.1 Planning 4.2 Design and development 4.3 Purchase 4.4 Production and service provision 4.5 Monitoring, measurement and analysis 4.6 Improvement 4.7 The complete audit cycle zas per ISO 19011 4.8 Overview of auditing principles 4.9 Definitions, planning, documentation requirements 4.10 Checklists 4.11 Execution, auditing techniques 4.12 Auditor qualities 4.13 Identifying non-conformities, NC writing techniques ***Syndicated Exercises on above***	