TUV India Training Academy

Webinar for Overview Program on ISO 13485 : 2016 - Medical Devices Management System

Date : 5th August 2020, Time: 10.30 am to 12.30 pm

Course Features

ISO 13485 – Medical Device – Quality Management Systems –Requirements for regulatory purpose – address the development, implementation and maintenance of quality management system intended for use by medical device manufacturers, developers, and suppliers. The standard details the requirement for quality management systems, to meet customer requirement and allows the incorporation of applicable regulatory requirements within an organization's quality management system.
The course will make participants understand of ISO 13485 Requirements and how to approach implementation.

Course Objectives

- Provide a basic understanding of ISO 13485 Standard's requirements
- Provide understanding on Integration of ISO 13485 requirements in ISO 9001 QMS.

Who should attend ?

- Management Representative for Medical Devices QMS
- QA Professionals in Medical Devices Field
- Core Team Members of Medical Devices – QMS Team
- Internal Auditors of Medical Devices QMS
- External Auditors of medical Devices QMS.
- Students having interests in Medical Devices

Course Contents

- Basic Introduction to ISO 13485: 2016
- Relation ISO 9001:2015 / ISO 13485:2016
- Key issues addressed by ISO 13485:2016
- Integration of Risk Management ISO 14971 in ISO 13485

ISO 13485:2016

Issue of Certificate

TUV India certificate of attendance shall be issued to all the delegates attending the course.

Duration : 120 Minutes (2 Hours)

Registration Fee : Rs. 1500 + 18 % GST Per Participant

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