TUV India Training Academy

Online Internal Auditor Training Program on ISO 13485: 2016 Medical Devices Quality Management System

Date : 28th to 29th January'2021, Time: 9:30AM to 5:30PM

Course Features

This course is designed to meet the requirement of competent auditors referred in ISO 19011. The course includes class room sessions coupled with syndicate group exercises to enhance delegate participation to achieve learning objectives.

Medical Devices - Quality Management System that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support).

Course Objectives

- To enable delegates understand Key concepts in Medical Devices - Quality Management Systems - Requirements for regulatory purposes auditing
- To impart/enhance practical auditing skills to become certified Internal Auditor
- To enable the delegates to plan, conduct & manage QMS internal audits in accordance with the principles & guidance of ISO 19011

Who should attend?

Generally anyone involved in Medical Devices Industry but specifically:

- Quality executives/managers
- R& D Personnel
- Regulatory Affairs personnel
- Management representatives
- QMS Consultants
- MD Importers
- MD Software developers/validators
- Personnel wishing to attend higher level courses such as Lead Auditor courses.

Course Contents

- Introduction to ISO 13485, History
- Classification of medical devices as per MDR and EU
- Overview of changes in ISO 13485:2016 with focus on QMS planning, leadership, risk based thinking, performance evaluation & improvement
- Introduction to auditing : definition, types of audits
- Internal audit planning & preparation
- Conducting internal audit & reporting non-conformities
- Corrective action & audit follow-up activities,
- Auditor attributes, competence & evaluation
- Individual / Syndicate exercises
- Written examination & summing-up

Prerequisite / Prior knowledge

- All delegates should have reasonably good understanding on quality management principles, concepts & basic requirements of ISO 9001:2015 and ISO 13485:2016
- It is desired but not essential to have regulatory background of medical devices
- Knowledge of English is essential
- All the delegates / participants must arrange their own hard copy of ISO 13485:2016 standard throughout the online program. This is essential requirement.

Issue of Certificate

Certificate of successful completion shall be issued to all the delegates who attend entire duration of the course and pass the online exam.

Duration: 8 Hours including 1 hour break for both days

Registration Fee : Rs. 5,000 + 18 % GST Per Participant

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