TUV India Training Academy

ISO 13485:2016 Awareness

Course Features

This course is designed for awareness of ISO 13485:2016. 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 - ISO 13485 : 2016 Requirements for regulatory purposes.

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,
- QMS system – Clause 4
- Management responsibility - Clause 5
- Resource Management Clause 6
- Product realization Clause 7
- Measurement analysis and improvement – Clause 8
- Benefit of ISO 13485
- 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.
- It is desired but not essential to have regulatory background of medical devices.
- Knowledge of English is essential.

Issue of Certificate

Certificate of participation shall be issued to all the delegates who attend entire duration of the course.

Duration

1 Day

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