TUV India Training Academy

ISO 13485:2016 Internal Auditor Training

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.

Issue of Certificate

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

Duration

2 Days

Registered & Head Office-
801, Raheja Plaza I, LBS Marg, Ghatkopar (W), Mumbai 400 086
Email: trainingindia@tuv-nord.com **Tel**: +91-22-66477000

Pune: training.pune@tuv-nord.com
Baroda: training.baroda@tuv-nord.com
Mumbai: training.mumbai@tuv-nord.com
Kolkata: training.kolkata@tuv-nord.com
Delhi: training.delhi@tuv-nord.com
Bengaluru: training.bengaluru@tuv-nord.com
Coimbatore: training.coimbatore@tuv-nord.com
Chennai: training.chennai@tuv-nord.com
Hyderabad: training.hyderabad@tuv-nord.com

Website: www.tuv-nord.com/in **Toll Free:** 1800-209-0902