TÜVINDIA

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CQI / IRCA Approved Lead Auditor Training Course on ISO 13485:2016 Medical Devices—Quality Management System

Course Features:

This is CQI/IRCA approved course on MDQMS – ISO 13485:2016 Lead Auditor Training (IRCA Course No. 2027). This course is in accordance with ISO 19011 and ISO/IEC 17021. The course includes understanding the elements of ISO 13485:2016 Medical Devices - Quality Management System (MDQMS) coupled with a practical approach to plan, effectively conduct and report first party, second party and third party audits of MDQMS which helps organizations to achieve their MDQMS objectives and improve overall MDQMS performance. The course focuses on imparting knowledge and developing skills in conducting audits of MDQMS effectively and independently as a team leader.

Course Objectives:

- To understand the overview of ISO 13485:2016 – Medical Devices - Quality Management System (MDQMS)
- To enable delegates understand key concepts in Medical Devices - Quality Management System (MDQMS) auditing
- To impart/enhance practical auditing skills to become certificated Lead Auditor
- To enable the delegates to plan, conduct and manage MDQMS audits effectively in accordance with the principles and guidelines of ISO 19011 and ISO/IEC 17021
- To enhance the technical and behavioral competency in conducting effective MDQMS audits as Lead Auditor

Who should attend ?

- Individuals aspiring to become certificated auditors/ lead auditors to make career in MDQMS auditing
- Medical device quality professionals interested in conducting first party, second party, and/or third party audits
- MDQMS management representatives
- Individuals responsible for managing the audit programs in their organization
- Departmental / functional MDQMS coordinators
- Existing internal auditors of MDQMS
- Quality directors, managers, and engineers
- Medical Devices - Quality Management System (MDQMS) Consultants

All the delegates / participants are expected to have basic knowledge of the principles and concepts of Medical Devices - Quality Management System (MDQMS) including awareness of the need for quality in medical devices, responsibilities, management commitments, terms, definitions and requirements of ISO 13485:2016.

Course Contents:

- CQI/IRCA Registration Scheme and benefits of becoming MDQMS Lead Auditor
- Medical Devices - Quality Management System (MDQMS) and its benefits
- Relevant standards, ISO 13485:2016, ISO 19011:2018, ISO/IEC 17021

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- The importance of Medical Devices — Quality Management System
- Developing Medical Devices - Quality Management System (MDQMS)
- Introduction to auditing MDQMS
- ISO 13485:2016 auditing techniques
- Managing and leading an ISO 13485:2016 audit team
- Interview techniques
- Recording and reporting nonconformities
- Audit reporting
- Corrective Action and Audit Close out process
- Continuous Assessment exercises and feedback
- Syndicate and role play exercises and feedback
- Examination as per CQI/IRCA requirements
- Sum-up

Certificate

Certificate of successful completion shall be issued to all the delegates/participants who attend entire duration of the course, in all the sessions and qualify in examination.

Duration

5 Days

About Us:

TUV India Pvt. Ltd. (TÜV NORD GROUP) is a customer-focused, innovative, and independent, technical, quality and safety services organization, dedicated to providing future-proof solutions through technological excellence for the success of its customers with the highest level of integrity. With a presence at over 40 strategic locations in India; a branch office in Sri Lanka and Bangladesh; state-of-the-art laboratories at Pune, Bengaluru, Noida and Jamnagar; 100 important countries worldwide and through digital means, we are always connected to you, our esteemed customer, anywhere, anytime.

We are proud to provide increasing levels of services to the best known, largest global and national companies as well as medium and small industries in diverse sectors like Oil and Gas, Petro-chemical, Nuclear, Renewables, Infrastructure, Food, Power, Manufacturing, Chemicals, Pharma, Paper, Automobiles, Railways, Aerospace, Defence, IT, Health, Hospitality, Retail, etc.

Over 1400 competent and experienced TUV India experts spread across India and over 14000 TUV NORD experts all over the world, enthusiastically support our clients by providing value-added services in Industry Inspection, European / International Approvals, Management System and IT Certification, Sustainability, Energy Audit, Water Audit, Carbon Services, Building Infrastructure and PMC, Renewable Energy, Food and Packaging Testing, Food Certification and Inspection; Testing of restricted and banned chemicals in Automotive and Electrical and Electronics components and other regulated industries, Product Testing — Electricals, Electronics and Industrial Machinery; Product Certification; Petroleum, Chemicals and Gas Cargo Inspection; Petroleum, Chemicals and Gas Testing; Railway Technology; Engineering, Safety Studies, and knowledge enhancing training programs under TUV India Training Academy.

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