EXEMPLAR GLOBAL, USA APPROVED
LEAD AUDITOR COURSE ISO 13485:2016

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NVT QUALITY CERTIFICATION INTERNATIONAL

GLOBAL CERTIFICATION AND TRAINING SERVICES

ISO 13485:2016
LEAD AUDITOR COURSE

Course Overview

- The purpose of this training course is to impart/enhance practical knowledge of ISO 13485:2016 standard and develop skills and expertise needed to audit/manage quality management system audits efficiently.
- This will enable participants understand the concepts of ISO 13485:2016 and how the standard can become a valuable part of your business management system through an exciting accelerated learning approach.
- This will provide participants with knowledge and skills required to perform first, second and third party audits of management systems against ISO 13485:2016, in accordance with the guidance provided in ISO 19011:2018 standard.

Course Duration

40 hours

Learning Objectives

- Describe the ISO 9000 family standards.
- Understand the requirements of ISO 13485:2016 standard
- Explain Key concepts in Environmental Management System auditing.
- Impart/enhance practical auditing skills to become internationally recognized certified Auditor/Lead Auditor
- Provide an understanding of process approach how it impacts auditing practices.
- Explain the role of an auditor to plan and manage a process based audit considering: resources and timing, use of checklists and selection of audit teams.
- Enable the participants to plan, conduct and manage ISO 13485:2016 external (second and third party) as well as internal audits in accordance with the principles and guidance of ISO 19011:2018.
- Gain audit skills and learn techniques for: evaluating, auditing, findings, communicating and presenting audit findings and preparation of reports.
- Identify and write nonconformity statements with insight of proposal corrective actions and undertake audit follow-up activities.

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Course Content

- Introduction
- Process approach, PDCA
- Medical Device Policy
- Medical Device Objectives, Objective Deployment
- Strategic Direction
- Overview of ISO 13485:2016
- Applicability of ISO 13485:2016 Medical Device Definition and Classification
- Regulation and Special Controls
- Safety and Effectiveness
- Technical Documentation and Submissions
- Introduction ISO 13485:2016
- ISO 19011:2018 explained
- Management, Operation and Support Processes
- Mandatory Documented Information
- Preparation, planning and conducting audits
- Audit reporting
- Reporting non-conformities
- Corrective action and follow up
- Requirements for registration
- Requirements for registration Continuous Assessment exercises and feedback
- Syndicate and role play exercises and feedback
- Written Examination

Pre-Requisites

Some specific ISO 13485:2016 knowledge and Min. 4 years working experience is required. This is an extensive course. Before staring this course, students are expected to have the following prior knowledge:

a.) Knowledge of the following environmental management concepts:

- The Plan , Do, Check, Act (PDCA) cycle.
- Process approach

b.) Some knowledge of the requirements of ISO 13485:2016.

Who Should Attend?

- This course is recommended for anyone who intends to perform audits of a Medical Device Management System.
- Management Representative
- Existing Internal Auditors of ISO 13485:2016.
- Medical Device Consultants.
- Individual responsible for implementing the ISO 13485:2016 standard.
- Staff with responsibility to evaluate the outcome of internal ISO 13485:2016 audits and who have responsibility/authority to improve the effectiveness of the ISO 13485:2016.
- Personnel wishing to make career in ISO 13485:2016 auditing.

NVT QC AT A GLANCE

Over 25 years experience

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