



**EXEMPLAR GLOBAL, USA APPROVED
ISO 13485:2016 INTERNAL AUDITOR COURSE
OFFERED BY RECOGNISED TRAINING PROVIDER
NVT QUALITY CERTIFICATION PVT. LTD., INDIA
(NVT QUALITY CERTIFICATION INTERNATIONAL, USA)**





ISO 13485:2016 INTERNAL AUDITOR COURSE



Course Overview

The aim of ISO 13485:2016 Internal Auditor Training Course is to provide to individuals and other professionals an understanding of ISO 13485:2016 standard and the skills to undertake effective first and second party audits.

A practical and interactive series of modules provides:

- Understanding the requirements of ISO 13485: 2016 standard
- Understanding auditing requirements of ISO 19011:2018 standard
- Carrying out first and second party auditing

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

Course Duration

24 hours

Who Should Attend?

The course is ideal for delegates involved in first and second party auditing and for individuals leading their organizations to registration/certification and for those managers holding the responsibility of implementing and managing the standard.

Learning Objectives

At the end of the course, delegates will have:

Knowledge:

- Understanding of ISO 13485:2016 and ISO 19011:2018 standard

Skills:

- To plan, conduct and report an audit as per ISO 19011:2018 standard
- To meet requirements for certification to ISO 13485: 2016 standard
- To verify conformance with statutory and regulatory requirements related to product

NVT QC AT A GLANCE

Over 25 Years experience

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Accredited by NABCB, India and ANAB, USA for certification of Quality management system of organizations.

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Recognized by EXEMPLAR GLOBAL as a training provider

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Presence in India, South East Asia, Middle East, Africa, Europe and USA

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Proven Leadership in certification and training programs

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Over 10000 + audits in AQMS, QMS, EMS, ISMS, OHSAS, EnMS and IMS



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