



ISO 13485:2016 LEADERSHIP (AWARENESS) COURSE

OFFERED BY RECOGNISED TRAINING PROVIDER
NVT QUALITY CERTIFICATION INTERNATIONAL



GLOBAL CERTIFICATION AND TRAINING SERVICES



ISO 13485:2016 LEADERSHIP (AWARENESS) COURSE



ISO 13485:2016

- The purpose of this training course is to impart/enhance practical knowledge of ISO 13485:2016.
- 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 understanding of the standard, knowledge & skills

Course Contents

- 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 & Classification
- Regulation & Special Controls
- Safety & Effectiveness
- Technical Documentation & Submissions
- Introduction ISO 13485:2016
- Management, Operation & Support Processes
- Mandatory Documented Information

Course Duration

8 hours

NVT QC AT A GLANCE

Over 25 years experience

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Accredited by ANAB and NABCB 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 USA, Europe, Middle East, Africa, South East Asia and India

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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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