

## Online Internal Auditor Training Program on ISO 13485: 2016 Medical Devices Quality Management System (Weekend Batch)

Date : 12th & 13th June 2021, Time: 9:30AM to 5:30PM

### 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.

**Registration Fee : Rs. 5,000 + 18 % GST**  
**Per Participant**

To know about all our Online Training Programs scan adjacent QR Code

**To Register and Pay : [Click Here](#)**

### **Registered & Head Office-**

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### 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
- ♣ All the delegates / participants must arrange their own hard copy of ISO 13485:2016 standard throughout the online program. This is essential requirement.

### Issue of Certificate

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

**Duration:** 8 Hours including 1 hour break for both days



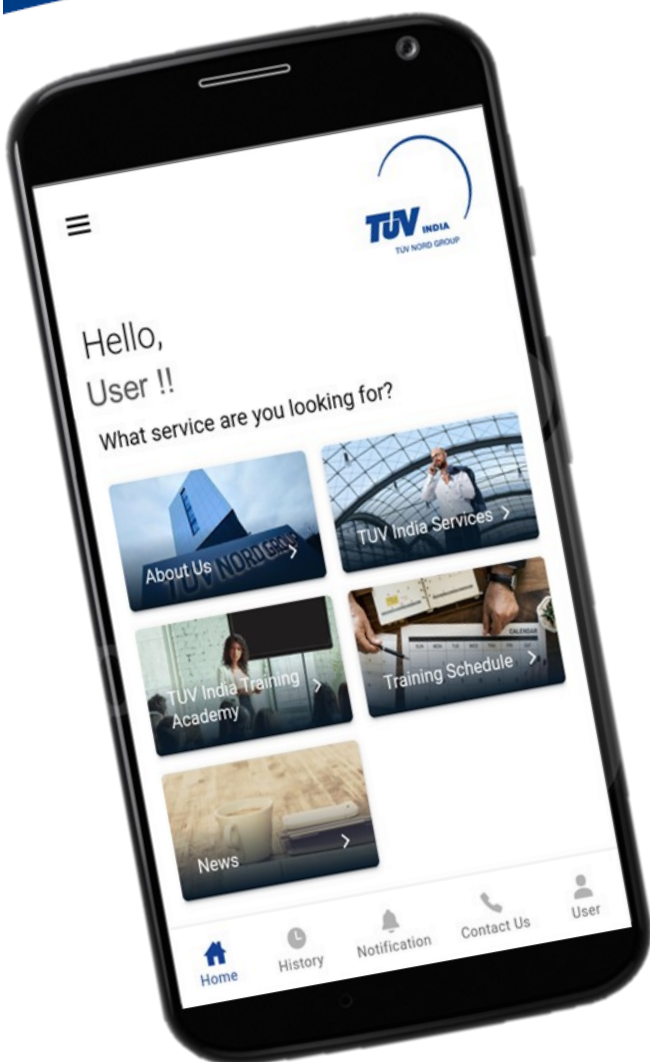
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Expertise for your Success

All our Online Training Offerings are for the resident of India & Sri Lanka Only.

# TUV India's Customer Friendly Mobile App

## TUV INDIA TRAINING ACADEMY (TITA)



**Our user friendly mobile application is developed to provide constant connect with our customers and participants along with hands-on information about the latest offerings of TUV India Training Academy. The app is also apprising the users on diverse service portfolio of TUV India along with latest developments related to our company.**

Some of the highlights of our app are:

- **Available on Android- Google Play Store & iOS Apple Store**
- **Provides overview about TUV India (TUV NORD GROUP), our services and latest developments**
- **Details about TUV India Training Academy offerings**
- **Training Schedules – both Class Room and Online Trainings**
- \* For each training, the app provides Course Features, Who should attend, Course Contents, Pre-requisites etc
- \* Link for Registering for the course of choice with integrated payment gateway
- \* Payment History (Receipts, Invoices)
- \* Certificates for attended programs based on user eligibility
- \* Notifications related to new offerings and sessions
- \* Contact us with linked email or phone (toll free number)
- \* Individual User Profile



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