

ISO13485:2016 Medical Devices- Quality Management System Internal Auditor Course

This course aims to equip participants with principles and concepts of ISO13485:2016 and competency to conduct an effective internal audit on ISO13485:2016 requirements.

DURATION
2 Days

LANGUAGE
English

COURSE CODE
MM-70621

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Course Content

The syllabus focuses on:

Day 1:

- Introduction to Quality Management Systems
- Overview of ISO 13485:2016 requirements
  - Section 4: Quality Management System
  - Section 5: Management Responsibilities
  - Section 6: Resources Management
  - Section 7: Product Realization
  - Section 8: Measurement, Analysis, and Improvement

Day 2:

- Audit planning and preparation
- Audit execution
- Non-conformity reporting
- Closing meeting
- Audit report preparation
- Audit follow-up

Who Should Attend:

Medical device quality professionals, Individuals interested in conducting first-party or second-party audits, Management Representatives, Quality Manager, Internal Auditors, Individual responsible for establishing, implementing, maintaining ISO13485:2016

Method of Training*

1. Online Webinar (With interactive activities using Mentimeter/Kahoot/Breakout rooms to equip learners with an active learning experience.)

2. Face-to-Face (Live interaction with the trainer during group discussions, operational case study, individual and group presentation on the course activities assigned.)

*Mode of training may vary based on Covid-19 advisory or pandemic situation. Please refer to the course registration form for the confirmed mode of training for the respective dates.

Certification

Certification will be issued to participants who have attended the course and have successfully completed the assessments.

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