

ISO13485:2016 Medical Devices- Quality Management System Awareness Course

This course aims to equip participants with principles and concepts of ISO13485:2016 requirements.

DURATION
1 Days

LANGUAGE
English

COURSE CODE
MM-70421

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Insightful Standards | Resourceful Collaboration

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Course Content

The syllabus focuses on:

- 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

Who Should Attend:

Medical device quality professionals, appointed staff who are involved in documentation control and individuals responsible for establishing, implementing, maintaining the Quality Management System as per 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 of Attendance will be awarded for participants who are with 100% attendance.

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