



# 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

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

## 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.

### ISRC PTE. LTD.

11 Eunos Road 8, #08-01A  
Lifelong Learning Institute,  
Singapore 408601

Tel (+65) 6747 4123  
Email [training@isrc.com.sg](mailto:training@isrc.com.sg)

### Certification

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