



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

ISO13485:2016 Medical Devices- Quality Management System Awareness Course

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.

ISRC PTE. LTD.

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

Tel (+65) 6747 4123
Email training@isrc.com.sg

Certification

Certification of Attendance will be awarded for participants who are with 100% attendance.