

ISO 13485:2016 MEDICAL DEVICES & INTERNAL AUDITOR TRAINING



Objectives

ISO 13485:2016 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

1. The functions & requirements of the ISO 13485:2016 Medical Devices standard
2. The understanding & implementing of the ISO 13485 Medical Devices standard effectively as to work instructions / standard operation procedure manuals requirements
3. Using ISO 13485 Medical Devices standard to drive towards becoming a quality class organisation

Duration

2 days | 9am – 5pm | 14 hours

Who should attend

Managers, executives, supervisors and management staff who want to gain knowledge on ISO 13485:2016 Medical Devices and staff who are likely or currently involved in implementing and maintaining ISO 13485:2003 and key personnel assigned for internal audits, management representatives (MR), etc.

Course Fees

Member: S\$537.84

Non-Member: S\$563.76

Registration Fee of S\$17.28 apply

SDF funding & SkillsFuture applicable

All fees stated are inclusive of 8% GST

Award of Certificate

Certificate of Completion will be issued to participants who have attended at least 75% of the course.



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Course Contents

The course includes a high level of interactivity during training on:

- Interpret all clauses of ISO 13485:2003
- Understand differences between ISO 13485:2003 and ISO 13485:2016
- Understand the Quality Management Principles
- Apply principles of the ISO 19011 to the auditing process
- Plan, conduct and report effective internal audits to the ISO 13485:2016

Key Benefits

A trained-combined system Internal Auditor with the skill set to:

- Conduct an internal audit of the ISO 13485 management system
- Enable your business to remain compliant with the requirements of the ISO 13485
- Follow through complex audit trails and identify any possible management systems discrepancies
- Identify any gaps that threaten the effectiveness of your management systems



Please refer to this URL
<https://www.sqi.org.sg/courses/>
or QR Code for soft copy
and updated training schedule

Membership Application

Register membership online at
www.sqi.org.sg/membership-join/
or contact us to get the membership
application form.

Membership Categories:

- ~ Organisation membership
- ~ Individual membership

SQI International is a subsidiary of Singapore Quality Institute (SQI). SQI operates as a non-profit professional institute that promotes and advances excellence in the field of quality in Singapore; and actively champions quality initiatives in the region and around the world through networking and collaborating with other international quality organisations.

SQI is a World Partner of the American Society for Quality (ASQ); and a Board Member of both the Asian Network for Quality (ANQ) and the World Alliance for Chinese Quality (WACQ).



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