



SINGAPORE QUALITY INSTITUTE

ISO 13485:2003 Medical Devices QMS & IQA

Objectives

- The functions & requirements of the ISO 13485:2003 Medical Devices QMS
- The understanding & implementing of the ISO 13485 Medical Devices QMS effectively as to work instructions / standard operation procedure manuals requirements
- Using ISO 13485 Medical Devices QMS to drive towards becoming a quality class organization

Who Should Attend

Managers, executives, supervisors and management staff who want to gain knowledge on ISO 13485:2003 Medical Devices QMS 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 Outline:

Chapter 1 – Main areas of difficulty

- ISO documentation requirements
- Confusion over processes
- What measuring equipment needs to be calibrated?
- Confusion over “Correction, Corrective Action & Preventive Action”

Chapter 2 – Assessment Requirements for ISO 13485:2003

- Introduction of the ISO 13485 Medical Devices QMS standard requirements
- Interpretation & implementation of the ISO 13485 Medical Devices QMS standard requirements
 1. Quality Management Systems
 2. Management Responsibility
 3. Resource Management
 4. Product Realization
 5. Measurement Analysis & Improvement

Chapter 3 – Audit Journey

- Audit
 1. Types of an audit, what is an audit? Why audit?
 2. Audit program, objectives, reasons for auditing
 3. Auditing behavior, language, independency, competence & experience

Chapter 4 – Four Phases of An Audit Program

- Preparation & Planning (audit team selection, audit schedule, audit plan and audit checklist, preliminary visit & audit team orientation)
- Performing an audit (opening meeting, typical life phases of a product, auditing, gathering objectives of audit, review of documentation, system audit)
- Reporting the audit results (non conformities, observations & questioning techniques, statistical methodology & summary of findings)
- Debriefing the auditee, follow-up corrective & preventive actions, closed meeting

FEES (inclusive of 2 tea breaks, training material & certificate of attendance)

Member: \$481.50

Non Member: \$577.80

All fee stated are inclusive of 7% GST.

Duration: 2-Day (9.00am – 5.00pm)

Venue: Singapore Quality Institute

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