COURSE TITLE

ISO 13485:2016 QMS AUDITOR & LEAD AUDITOR TRAINING

Introduction

ISO 13485 is an international standard that outlines the requirements for a Quality Management System in the medical device industry. This standard is specific to medical devices and covers the entire life cycle of a device, from design and development to production, installation, and servicing. It is intended to ensure that medical devices are safe and effective for their intended use.

Course Fee

Member: S$1,979.44
Non-Member: S$2,197.44
Price inclusive of Registration Fee of S$17.44

*All fees stated are inclusive of 9% GST

OBJECTIVES

Participants for this course will be able to:

- Focus on the appreciation of ISO 13485, ISO 19011 and ISO/IEC 17021-1 Standard requirements.
- Strengthen the foundation of audit methodology, skill and techniques to perform First-Party & Second-Party Audits and draw audit conclusions based on audit findings.
- Learn how to lead an audit team, conduct opening & closing meetings, collection of audit evidence against audit criteria and to present audit findings and audit conclusion.

SINGAPORE QUALITY INSTITUTE

WHO SHOULD ATTEND

Executives, Supervisors, Engineers, Managers, Quality Professionals & Management Consultants who are engaged as First-Party & Second-Party Auditor / Lead Auditor

2024

Course Brochure

ISO STANDARDS COURSES - ISO 13485:2016

COURSE CONTENTS

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

- **Understanding the requirements of ISO 13485:2016, ISO 19011:2018 & ISO/IEC 17021:2015 Standards**
- **Application of PDCA Cycle, Process Approach and Risk-based Thinking Approach**
- **Assess the capability of the measuring equipment to achieve the desired degree of accuracy**
- **Interpretation of Process Validation (Installation (IQ) / Operational (OQ) / Performance (PQ) Qualification**
- **Terms & Definition: Audit, Audit Objective / Scope / Criteria / Evidence / Findings & Conclusion**
- **Seven Principles of Auditing and their Application**
- **Audit Plan vs Audit Program / Management of an Audit Program**
- **Six Essential Steps in performing an Audit**
- **Responsibilities and Authorities of Auditor and Lead Auditor**
- **Prepare Audit Program, Audit Plan, Audit Checklist and Corrective Action Form**
- **Execution of Audit by applying the Six Key Points of Audit Methodology**
- **Documenting Non-conformity / Non-compliance, Corrective Action & Follow up Verification Audit**
- **Analysis and Presentation of Audit Findings and Audit Conclusion**
- **Desk-top audit session (case study with role play)**

TRAINER

This course is conducted by registered lead auditors with IRCA, UK with past certification background and who have accumulated many years of conducting audits on various industries both in Singapore, Malaysia, Indonesia, China, Taiwan and in the region. With the practical case reviews specially arranged, the participants can appreciate the skills learnt through effective conducting and reporting of an audit against the ISO 13485:2016 standard requirements.

AWARD OF CERTIFICATE

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

DURATION

5 days
9am - 5pm
35 hours

CONTACT

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