COURSE TITLE

ISO 13485:2016 MEDICAL DEVICES & INTERNAL 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: $782.62
Non-Member: $867.64

All fees stated are inclusive of Registration Fee & 9% GST

OBJECTIVES

Provide participants with the knowledge on:

- The functions and requirements of the ISO 13485:2016 Medical Devices standard
- The understanding and implementing of the ISO 13485:2016 Medical Devices standard effectively to Work Instructions / Standard Operation Procedure manuals requirements.
- Using ISO 13485:2016 Medical Devices standard to drive towards becoming a quality class organization.

SINGAPORE QUALITY INSTITUTE

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 13485:2016 and key personnel assigned for internal audits, management representatives (MR), etc.

2026

Course Brochure

ISO STANDARDS COURSES – ISO 13485:2016

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

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

2 days
9am - 5pm
14 hours

CONTACT

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