

ISO 13485:2016 AWARENESS & INTERNAL AUDIT TRAINING



HYBRID TRAINING

15 & 16 Dec 2026 (Tue & Wed)

- Remote Online Training (Zoom) &
- Dorsett Grand Subang Hotel, Selangor (Physical)

**** Choose either Zoom OR Physical Session**

OBJECTIVES

The training provides:

1. Understand the guidelines of QMS auditing accordance to ISO 19011:2018 and internal audit process from initiating, preparing, conducting audit activities, preparing and distributing the audit report
2. Understand the application of the risk-based approach in medical device QMS and implement during the internal audit
3. To handle the non-conformance effectively and help the client understand the clause of ISO 13485:2016 requirements
4. To Develop your knowledge of how the requirements of respective standard like ISO 13485:2016 are fulfilled and help the organization to fulfil the regulatory requirements.

FOR WHOM

This course is designed for individuals involved in the auditing, maintaining and monitoring of QMS against ISO 13485:2016

REGISTER 3 PAX, FREE 1 SEAT



OUR SOLUTIONS

- ✓ This course can be run in-company around the world
- ✓ We can tailor the content to focus on your requirements.
- ✓ This approach makes perfect sense for groups of 4+ delegates, enhancing cost effectiveness as well as team bonding.
- ✓ Classroom accompanied by Lectures, real Experience Sharing, Role-plays, Interactive Group Activities, Experiences, Simulation Activities and Feedback
- ✓ Delegate manuals and certificates of Attendance will be provided

14 hours ZOOM & PHYSICAL Program



COURSE OVERVIEW

INTRODUCTION

This course provide the participants with the knowledge and skills to conduct the internal audits of the QMS based on the relevant audit criteria like ISO 13485:2016. Participants will learn how to use risk based approach in the internal audit and learn how to report on the effective implementation and maintenance of management system in accordance with ISO 19011.

HOW YOU WILL BE BENEFIT

- Prepare, conduct and follow up on respective standard like ISO 13485:2016 audit activities
- The role of internal audit in maintaining and improving QMS with reference to the Plan, Do, Check, Act (PDCA) cycle
- Gain the skill to assess an organization's capability to manage its QMS by using ISO 13485:2016 clauses interpretation.
- Handle the non-conformity effectively based on the real life example from the auditor perspective
- Gain the skill to assess an organization's capability to manage its QMS by using risk- based approach
- Handle the non-conformity effectively based on the real life example from the auditor perspective and translate into risk management

COURSE CONTENT

DAY 1

Module 1: Regulatory Aspects

- Potential benefits of ISO 13485 from the regulatory perspective

Module 2: ISO 13485:2016 summary

- Main changes and focus of the new version
- Clarification of Concept like risk-based application
- Summary of clause 4,5,6,7,8 of ISO 13485.
- Case study for mock internal audit Preparation

Module 3: Introduction to Auditing

- Potential benefits of internal auditing from the auditor perspective
- Understand the auditor competence and Responsibilities

Module 4: The Process Approach and Process Auditing

- Understanding and meeting the requirements
- Looking at process in terms of added value and Obtaining results of process performance

DAY 2

Module 5: Non-conformity management

- Understanding the standard requirement based on the real-life example of non-conformity
- Case study

Module 6: Managing audit program

- Understand the Plan, Do, Check, Act Cycle

Module 7: Practical internal audit

- Applying the risk-based approach in audit
- Testing the understanding on the standard requirement
- Prepare audit conclusion and report
- Conduct audit follow up
- Q&A session