

MS ISO 13485:2017 MEDICAL DEVICES INTERNAL AUDITING (Code: MD03)

Duration: 2 Days

PROGRAMME OVERVIEW

Internal Audit is part of the requirement in the MS ISO 13485:2006 Standard as a process to verify overall MS ISO 13485:2006 implementation in organization to ensure its compliance to the standard and regulatory requirements and also as fact-based guidance for organization to improve.

This course describes concepts of the MS ISO 13485:2006 standard and the principles and practices of effective internal audits in accordance with ISO 19011:2002, "Guidelines for Quality and/or Environmental Management Systems Auditing." This course will include the explanation of MS ISO 13485:2006 clauses in detail and guide participants through internal audits steps by steps of audit process.

OBJECTIVES

- Understand the concept of Internal Audit in ISO 13485
- Understand the compliance to ISO 13485 requirement and how to conduct audit effectively
- Understand the requirement to be ISO 13485 Internal Auditor
- Be able to conduct audit effectively based on the correct audit technique and sampling
- Be able to evaluate NCR and write report correctly
- Understand how to verify corrective action in follow up NCR

COURSE CONTENTS

- Terms and definition in Internal Audit
- Overview of MS ISO 13485:2006 Standard requirements
- Effective Audit Planning & Preparation
- Executing of audit, evaluation of NCR and Report writing
- Corrective Action and Follow Up

WHO SHOULD ATTEND?

Managers, executives, engineers, professionals and employees involved in establishing, developing and implementing ISO 13485 Standards in the company and others whose job function will ultimately related.



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