



# SS 620:2016 Good Distribution Practice for Medical Devices Internal Auditor Course

This course aims to equip participants with principles and concepts of SS 620:2016 and competency to conduct an effective internal audit on SS 620:2016 requirements.

**DURATION**

2 Days

**LANGUAGE**

English

**COURSE CODE**

MM-70221

# SS 620:2016 Good Distribution Practice for Medical Devices Internal Auditor Course

## Course Content

The syllabus focuses on:

### Day 1

- Overview of SS 620:2016 requirements
- Reason for changes from previous HSA TS-01 to SS 620
- Understanding Requirements of Quality Management System - Organization Context
- Documentation Control
- Support and Resource Management
- Operation Control (i.e., Storage, Premises and Facilities, Delivery, Installation and Servicing Activities, Calibration, Return and Disposal of Medical Devices)
- Secondary Assembly
- Traceability of medical devices
- Management of non-conforming medical devices
- Complaint handling and Field Safety Corrective Action
- Management of Outsourced Activities

### Day 2

- Auditing Principles
- Audit Objectives
- Internal Audit Processes:
  - (A) Stage 1: Audit Preparation
    - ISO 19011:2018 Guideline for Auditing Management Systems
    - Determine Audit Scope
    - Forming Audit Team
    - Establish Audit Plan
  - (B) Stage 2: Conduct of Audit
    - Evidence Gathering, Interview, Site Inspection & Document Review
    - Triangulation of Facts
    - Categories of Audit Findings
  - (C) Stage 3: Report Findings and Follow Up
    - Closing Meeting
    - Writing audit finding statement
    - Preparation of Audit Report
    - Follow up on Corrective Action on audit findings closure

### Who Should Attend

Quality Manager, SS 620:2016 Appointed Internal Auditor, Individual responsible for establishing, implementing, maintaining SS 620:2016

### Method of Study

Our participants benefit from a learner-centred approach based on active-learning and problem-centric principles.

This is conducted through active participation methods such as role-playing, group discussion, quiz, and feedback. Problem-based learning enables participants to find solutions to issues through case studies, classroom discussion, and sample templates.

### Assessment & Certification

Certification will be issued to participant who attend the course and successfully complete the assessments.

### ISRC PTE. LTD.

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