SS 620:2016 (2021) Good Distribution Practice for Medical Devices – Requirements & Internal Auditor Training Course

INTRODUCTION

It is essential to equip our people who is playing the leading role in an organization with appropriate understanding and appreciation in the application of SS 620:2016 (2021) Good Distribution Practice for Medical Devices – Requirements in order to lead and supervise their subordinates on the shop-floor effectively and efficiently.

COURSE OBJECTIVE

(a) To equip the participants with the basic knowledge and skills to implement Good Distribution Practice for Medical Devices into their business operation.

(b) To enable the participants to conduct their internal audit in accordance with ISO 19001:2018 Guidelines.

Course Duration

2 days | 9am – 5pm | 14 hours

WHO SHOULD ATTEND?

This program is designed for Supervisors, Executives, Engineers and Managers who are involved in managing the day-to-day operational activities and engaged in routine internal audits.

Course Fees

Member: S$782.62
Non-Member: S$867.64

Registration Fee of S$17.44 apply

All fees stated are inclusive of 9% GST

Award of Certificate

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

COURSE CONTENT

Day One: SS620:2016 – Good Distribution for Medical Devices-Requirements

1. Scope
2. Normative References
3. Terms and Definitions
4. Quality Management System
5. Management Responsibility
6. Resource Management

7. Premises and Facilities
8. Secondary Assembly
9. Traceability
10. Counterfeit, Adulterated, Unwholesome or Tampered Medical Devices
11. Complaint Handling
12. Field Safety Corrective Action (FSCA)
13. Internal Audit
14. Outsourced Activities
15. Class-room Exercise & Discussion

Day Two: ISO 19011:2018 Guidelines for Auditing

Part 1: Auditing Requirements

- Terms & Definition: Audit, Audit Objective, Audit Scope, Audit Criteria, Audit Evidence, Audit Findings & Audit Conclusion
- Seven Principles of Auditing
- Audit Plan vs Audit Programme
- Management of An Audit Programme
- Six Steps in Performing an Audit
- Prepare Audit Plan and Audit Check Sheet
- Execution of Audit by applying “6A” Auditing Approach
- Documenting Non-conformity / Non-compliance, Corrective Action & Follow up Verification Audit
- Brief Outlines of Internal Quality Audit Procedure
- Human Aspect of Auditing
- Preparatory Work for External Audit
- Group Assignment & Presentation

Part 2: Auditing Exercise

- Preparation of Audit Checklist
- Audit Assignment: Role Play
- Drafting of Corrective Action Request