Quality LearningHub & Consultancy Singapore
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SS 620:2016 GDPMDS Requirements & Internal Auditor Training Course

The SS 620 certification aims to ensure that companies dealing with medical devices have a quality management system in place. The purpose of these quality management systems is to streamline the supply chain, ensuring that the quality and integrity of the medical devices is maintained throughout the storage and distribution process, thus providing quality assurance while safeguarding consumers interest and enhancing their confidence level.

It is commonly agreed that companies within the medical device industry will be subjected to strict external and internal audit. This kind of scenario makes SS 620 certification even more vital because it serves as quality manuals for companies. Such assurance from the certification can also ensure clear and timely documentation when the time arises for an audit to be conducted.

Having a robust set of practice for medical devices is essential to companies dealing with this kind of product because the confidence that consumers get from the certification will indirectly affect companies' profits and revenues.

Course Objectives:

Upon completion of the course, participants will be able to:

- Acquire knowledge requirements on handling medical devices.
- Knowledge of medical device fundamentals.
- Implementation of GDPMDS in medical device manufacturing firms.
- Understand, implement & comply with SS620:2016 in the organisation.
- Prepare and execute the internal audit.
- Implement corrective and follow-up actions to improve GDPMDS efforts.
- Continually improve GDPMDS.

Course Contents:

- Overview of SS 620:2016 Requirements
- Understanding Requirements of Quality Management System – Organisation Context
- Documentation Control
- Support and Resource Management
- Operation Control
- Secondary Assembly

- Traceability of medical devices
- Management of non-conforming medical devices
- Complaint handling and Field Safety Corrective Action
- Outsourced Activities
- Auditing Principles
- Internal Audit Processes:
  a) Audit Preparation
     - Determine Audit Scope
     - Forming Audit Team
     - Establish Audit Plan
  b) Conduct of Audit
     - Evidence Gathering, Interview, Site Inspection & Document Review
     - Categories of Audit Findings
  c) 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:

- Managers / Executives / Personnel who are involved in organizing and conducting internal audits for GDPMDS
- Personnel who are involved in the implementation and maintenance of SS GDPMDS or those who wish to know more about the specification and its requirements.

Training Methodology:

- Interactive Lectures
- Group Activity and Presentation
- Practical Exercises
- Case Studies
- Group Discussion
- Participants will receive comprehensive course manuals with reference materials.

Award of Certificate:

Certificate of Successful Completion will be issued to participants with at least 75% attendance.

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Duration:

2 days (14 hours)

Course Fee:

$600 nett per trainee (GST is not applicable).