

SS 620:2016 GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES & INTERNAL AUDITOR COURSE



Objectives

The SS 620:2016 (GDPMDS) serves as a guide on the quality management system for organisations involved in handling, storage, delivery, installation, servicing, secondary assembly and other related activities of medical devices and IVDs. The purpose of this course is to allow business owners, management representatives, internal auditors and any relevant personnel to have a good understanding of the new SS 620:2016 requirements as well as learning how to perform an internal audit.

For wholesalers and importers of medical devices in Singapore, it is a requirement to complete a 3rd party audit and attain the SS 620:2016 GDPMDS certification before applying for the dealers' license issued by the Health Sciences Authority (HSA) of Singapore.

Duration

2 days | 9am – 5pm | 14 hours

Who should attend

- Decision makers on management system strategy
- Quality managers, executives, management representatives or any personnel within an organisation wants to setup and implement business processes based on the new SS 620:2016 for the first time, or transiting from the existing HSA TS-01 (GDPMDS).
- Personnel who are involved in organising and conducting internal audits for SS 620:2016 GDPMDS.

Award of Certificate

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

Course Contents

In this course, attendees would also be able to experience the use of a software tool to setup and customise a set of documents that is relevant for their organisation.

- Introduction to SS 620:2016 (GDPMDS)
- SS620:2016 requirements versus TS-01: R 2.1 requirements
- SS620:2016 standards requirements - with evidence of clause reference for the audit purposes
- Planning and conducting an audit
- Reporting the audit
- Undertaking audit follow-up activities
- Application of software tool to setup and customise a set of QMS documents based on the SS 620:2016 requirements, and learning how to implement the processes.
- Planning and performing an internal audit using the audit schedule and checklist

Course Fees

Member: S\$535.00

Non-Member: S\$567.10

Registration Fee of S\$17.12 apply

All fees stated are inclusive of 7% GST



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Membership Application

Register membership online at www.sqi.org.sg/membership-join/ or contact us to get the membership application form.

Membership Categories:

- ~ Organisation membership
- ~ Individual membership

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