# INTERPRETATION & APPLICATION OF 21 CFR 820


## Introduction

**Title 21: Food and Drug**
**Part 820: Quality System Regulation**
Current Good Manufacturing Practice (cGMP) requirements are set forth in this quality system regulation.
The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labelling, storage, installation, and servicing of all finished devices intended for human use.
The requirements in this part are intended to ensure that finished devices will be safe and effective in compliance.

## Learning Objectives

This program is designed to equip the participants with the practical knowledge to interpret 21 CFR 820 with a view to establish and integrate the Quality System Regulation into the ISO 13485:2016 Quality System Documentation effectively for the manufacture of Medical Devices.

## Duration

2 days | 9am – 5pm | 14 hours

## Who should attend

This program is designed for R&D, Technical, QC/QA/RA, Engineering and Production personnel who are involved in implementing 21 CFR Part 820 in their manufacturing environment.

## Entry Requirement

Basic understanding on ISO 9001:2015 and/or ISO 13485:2016 Quality System Requirements is preferred.

## Course Fees

Member: S$918.00
Non-Member: S$972.00
*Registration Fee of S$17.28 apply*
*All fees stated are inclusive of 8% GST*

## Award of Certificate

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

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## Course Contents

**I. Brief Introduction To ISO 13485:2016: Medical Devices - QMS**
- Requirements For Regulatory Purposes

**II. Part 820: Medical Device – Quality System Regulation**

Subpart A--General Provisions
- 820.1 - Scope.
- 820.3 - Definitions.
- 820.5 - Quality system.

Subpart B--Quality System Requirements
- 820.20 - Management responsibility.
- 820.22 - Quality audit.
- 820.25 - Personnel.

Subpart C--Design Controls
- 820.30 - Design controls.

Subpart D--Document Control
- 820.40 - Document controls.

Subpart E--Purchasing Controls
- 820.50 - Purchasing controls.

Subpart F--Identification and Traceability
- 820.60 - Identification.
- 820.65 - Traceability.

Subpart G--Production and Process Controls
- 820.70 - Production and process controls.
- 820.72 - Inspection, measuring, and test equipment.
- 820.75 - Process validation.

Subpart H--Acceptance Activities
- 820.80 - Receiving, in-process, and finished device acceptance.
- 820.86 - Acceptance status.

Subpart I--Nonconforming Product
- 820.90 - Nonconforming product.

Subpart J--Corrective and Preventive Action
- 820.100 - Corrective and preventive action.

Subpart K--Labelling and Packaging Control
- 820.120 - Device labelling.
- 820.130 - Device packaging.

Subpart L--Handling, Storage, Distribution, and Installation
- 820.140 - Handling.
- 820.150 - Storage.
- 820.160 - Distribution.
- 820.170 - Installation.

Subpart M—Records
820.180 - General requirements.
820.181 - Device master record
820.184 - Device history record
820.186 - Quality system record
820.198 - Complaint files.

Subpart N—Servicing
- 820.200 - Servicing.

Subpart O--Statistical Techniques
- 820.250 - Statistical techniques

**III. Technical Aspects of the Quality System Regulation:**

(1) Design Controls
- ♦ Product Design Input & Product Design Review
- ♦ Product Design Output & Product Design Verification
- ♦ Process Design Input & Process Design Review
- ♦ Process Design Output & Process Design Verification
- ♦ Product & Process Design Validation
- ♦ Product & Process Design Transfer
- ♦ Product & Process Design Change
- ♦ Design History File

(2) Production and Process Controls
- ♦ Application of Statistical Control Techniques: Control Charts
- ♦ Computation & Interpretation of Pp, PpK, Cp & CpK
- ♦ Determination of Measurement System Capability: Discrimination Ratio, GRR% & ndc
- ♦ Establish Effective Calibration System: Reference Standard, Reference Materials, Measurement Error, Correction Factor, Measurement Uncertainty & Measurement Traceability
- ♦ Process Validation Protocol & Techniques: IQ (Installation Qualification), OQ (Operational Qualification) & PQ (Performance Qualification)

(3) Records
- ♦ Review and Compilation of Device Master Record
- ♦ Review and Compilation of Device history record.
- ♦ Review and compilation of Complaint files.

**Assessment**

Classroom Exercises and Assessment Tests

Please refer to this URL
https://www.sqi.org.sg/courses/
or QR Code for soft copy
and updated training schedule

### 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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TÜV SÜD ISO 9001 CERT NO.: 2012-1-0818 ISO 9001 : 2015

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