

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, labeling, 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: \$1,076.92
Non-Member: \$1,194.64

All fees stated are inclusive of Registration and Exam. Fee & 9% 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

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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 Control

Subpart E - Purchasing Controls

820.50 - Purchasing Controls

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820.60 - Identification

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Subpart G - Production and Process Controls

820.70 - Production and Process Controls

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820.80 - Receiving, in-process, and finished device acceptance

820.86 - Acceptance status

Subpart I - Non-conforming Product

820.90 - Non-conforming Product

Subpart J - Corrective and Preventive Action

820.100 - Corrective and Preventive Action

Subpart K - Labeling and Packaging Control

820.120 - Device labeling

820.130 - Device packaging

Subpart L - Handling, Storage, Distribution, and Installation

820.140 - Handling

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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

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 application form.

Membership Categories:

- ~ Organisation membership
- ~ Individual membership

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