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QSR 21cfr Part 820, ISO 13485

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Quality System (QS) Regulation/Medical Device Good Manufacturing Practices

- for FDA-regulated products
- manufacturers must establish and follow quality systems
- to ensure that products consistently meet applicable requirements and specifications

current good manufacturing practices (cGMP's), final rule on July 21, 1978

regulation effective on December 18, 1978, codified under part 820

federal register

Monday
October 7, 1996

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 808, 812, and 820
Medical Devices; Current Good Manufacturing Practice (CGMP); Final Rule

INTERNATIONAL STANDARD

ISO 13485

Second edition
2003-07-15

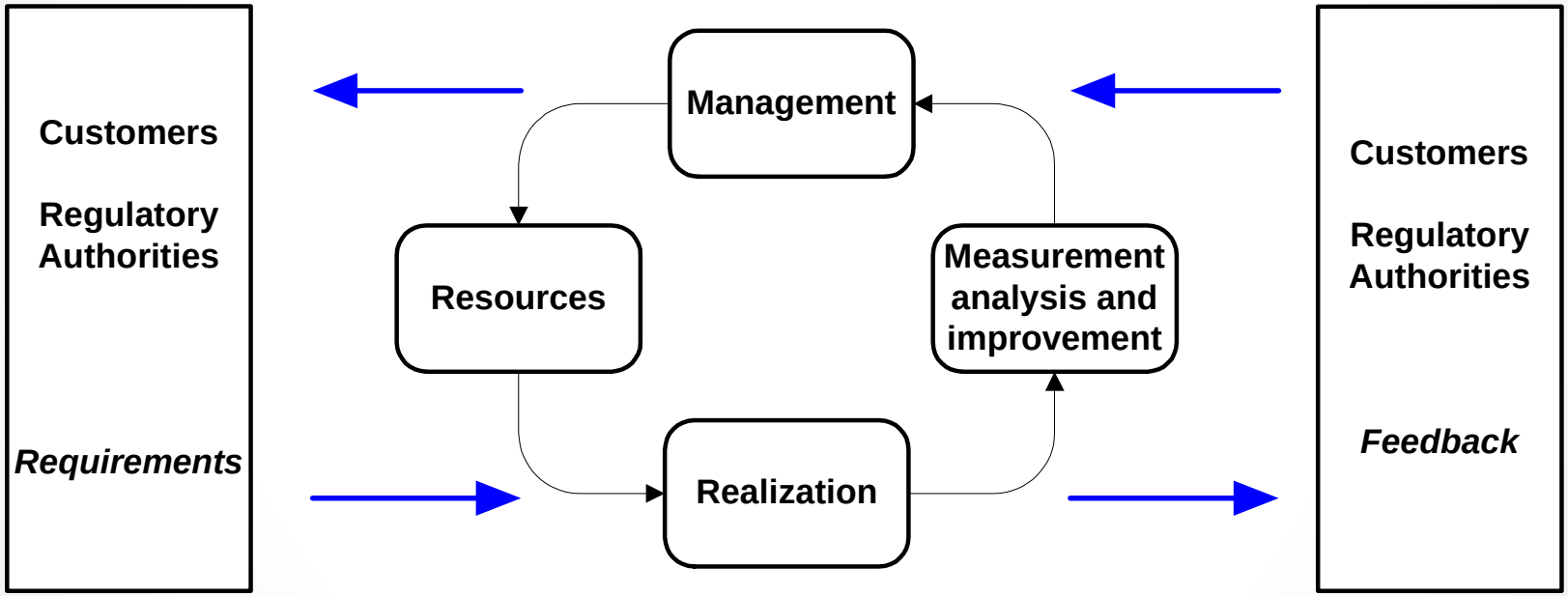
Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

ISO 13485 - Structure

0. Introduction
1. Scope
2. Normative references
3. Terms and definitions
4. Quality Management System
5. Management responsibility
6. Resource Management
7. Product realization
8. Measurement, analysis and improvement

Process-based quality management system - ISO 13485



Quality Management Subsystems

21 CFR 820 Quality System Regulation

Subpart A	General provisions
Subpart B	Quality System Requirements
Subpart C	Design Controls
Subpart D	Document Controls
Subpart E	Purchasing Controls
Subpart F	Identification and Traceability
Subpart G	Production and Process Controls

21 CFR 820 Quality System Regulation

Subpart H	Acceptance Activities
Subpart I	Nonconforming Product
Subpart J	Corrective and Preventive Action
Subpart K	Labeling and Packaging Control
Subpart L	Handling, Storage, Distribution and Installation
Subpart M	Records
Subpart N	Servicing
Subpart O	Statistical Techniques

Quality By Design

- Quality, Safety and Effectiveness must be designed and built into the product
- Inspection or testing of the end product alone is inadequate
- Each step must be controlled to ensure that the end product meets all specifications

Sec. 820.30 Design controls

b) Design and development planning
c) Design input
d) Design output
e) Design review
f) Design verification
g) Design validation
h) Design transfer
i) Design changes
j) Design history file

7.3 Design and development

7.3.1 Planning

a) design and development stages

b) review, verification, validation and design transfer activities

c) responsibilities

Planning output documented

7.3 Design and development

7.3.2 Design and development inputs

a) functional, performance and safety requirements
b) regulatory requirements
c) previous similar design
d) other essential requirements
e) outputs of risk management

7.3 Design and development

7.3.3 Design and development outputs

a) satisfactory input requirements

b) information for purchasing, production and for service provision

c) product acceptance criteria

d) characteristics of the product

Records for design outputs maintained

7.3 Design and development

7.3.4 Design and development review

a) results ability to meet requirements

b) problems identified, necessary actions

Participants include representatives of concerned functions, and other possible specialist

7.3 Design and development

7.3.5 Design and development verification

- obtained outputs ⇔ required inputs
- verification
- actions
- records

7.3 Design and development

7.3.6 Design and development validation

- accordance with planned arrangements
- before first delivery
- necessary actions
- clinical evaluation
- performance evaluation ⇔ intended use
- records

7.3 Design and development

7.3.7 Control of design and development changes

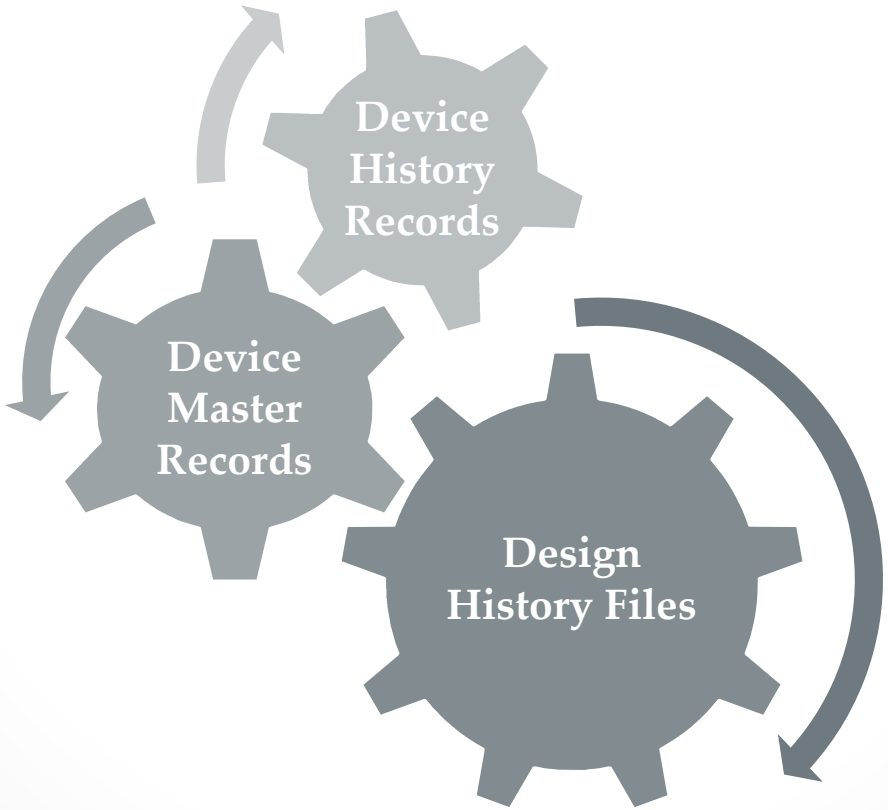
- identification
- verified & validated
- impacts
- necessary actions
- records

Verification versus validation

Verification is a detailed examination of aspects of a design at various stages in the development

Validation is a cumulative summation of all efforts to assure that the design will conform with user needs and intended use(s)

The QS Regulation requires the manufacturer to maintain main records such as:



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