FDA U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Proposed Rule
Medical Devices; Quality System Regulation Amendments
21 CFR 820

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Proposed Rule:
Medical Devices; Quality System Regulation Amendments

FDA published the proposed amendment to 21 CFR Part 820: Medical Devices; Quality System Regulation Amendments, on February 23, 2022; harmonizing the current Quality System regulation for medical devices by converging its requirements with international quality management system requirements

Revisions to Part 820 replace most of the existing regulation with an incorporation by reference (IBR) to the 2016 edition of International Organization for Standardization (ISO) 13485 - *Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes*

The proposed rule was open for public comment until **May 24, 2022.** FDA is reviewing the comments and will draft a final rule.

Overview of the Proposed Rule

- Withdraws most of the requirements in the current part 820
  - Retains the scope and a number of the definitions from the current part 820
  - Proposes to amend the title to the Quality Management System Regulation (QMSR)

- Incorporates by reference ISO 13485:2016
  - Minimal called out provisions to ensure consistency with other applicable FDA requirements
    - Includes definitions, clarifying concepts, and requirements

- Includes conforming edits to Part 4 (cGMPs for combination products)
  - Does not impact the CGMP requirements for combination products

Overview of Similarities and Differences

QS Regulation	ISO 13485:2016	Proposed Rule
Subpart A- General Provisions	Clause 1. Scope Clause 4. Quality Management System	Requirements substantively similar
Subpart B- QS Requirements	Clause 4. Quality Management System Clause 5. Management Responsibility Clause 6. Resource Management Clause 8. Measurement, Analysis, & Improvement	Requirements substantively similar
Subpart C- Design Controls	Clause 7. Product Realization	Requirements substantively similar
Subpart D- Document Controls	**Clause 4. Quality Management System**	**Differences addressed in 820.35**
Subpart E- Purchasing Controls	Clause 7. Product Realization	Requirements substantively similar
Subpart F- Identification and Traceability	Clause 7. Product Realization	Requirements substantively similar
Subpart G- PP&C	Clause 4. Quality Management System Clause 6. Resource Management Clause 7. Product Realization	Requirements substantively similar
Subpart H- Acceptance Activities	Clause 7. Product Realization Clause 8. Measurement, Analysis, & Improvement	Requirements substantively similar
Subpart I- Nonconforming Product	Clause 8. Measurement, Analysis, & Improvement	Requirements substantively similar
Subpart J- CAPA	Clause 8. Measurement, Analysis, & Improvement	Requirements substantively similar
Subpart K- Labeling and Packaging Control	**Clause 7. Product Realization**	**Differences addressed in 820.45**
Subpart L- Handling, Storage, Distribution, and Installation	Clause 7. Product Realization	Requirements substantively similar
Subpart M- Records	**Clause 4. Quality Management System**	**Differences addressed in 820.35**
Subpart N- Servicing	**Clause 7. Product Realization**	**Differences addressed in 820.35**
Subpart O- Statistical Techniques	Clause 7. Product Realization Clause 8. Measurement, Analysis, & Improvement	Requirements substantively similar

Structure of the Proposed QMSR

820.1 Scope.

820.3 Definitions.

820.7 Incorporation by reference.

820.10 Requirements for a quality management system.

820.15 Clarification of concepts.

820.35 Control of records.

820.45 Device labeling and packaging controls.

Definition Changes (§820.3)

Withdrawing	Retaining from QS reg	Adding	Clarify/ Supersede	Retain with modification
Establish	*Act*----> **FD&C Act**	Customer	*Medical device*---> **Device**	Rework: removing the reference to device master record (DMR)
	Management with executive responsibility----> **Top Management**		*Labelling*---> **Labeling**	Product: retaining, but adding 'service' to the definition
	Process Validation-----> **Validation of processes**			
	• Component • Finished device • HCT/P • Design validation • Remanufacturer • Nonconformity • verification			
	Manufacturer			

Applicable Regulatory Requirements

(§820.10)

Requirement to comply with other applicable requirements:

- 21 CFR Part 830: Unique Device Identification Requirements (Clause 7.5.8)
- 21 CFR Part 821: Traceability Requirements, if applicable (Clause 7.5.9)
- 21 CFR Part 803: Reporting to Regulatory Authorities (Clause 8.2.3)
- 21 CFR Part 806, Advisory Notices (Clauses 7.2.3, 8.2.3, 8.3.3)

Traceability

- Add a requirement to ensure that devices that support or sustain life, comply with the traceability requirements, in addition to just implantable devices as outlined in Clause 7.5.9.2

Clarification of Concepts

(§820.15)

Organization

- Clarify the term also includes the meaning of the term manufacturer as defined in the proposed §820.3

Safety and Performance

- Where safety and performance is used, it shall be construed to mean the same as “safety and effectiveness”

Validation of processes

- Clarify the term as used in ISO 13485 to refer to “process validation” as defined in the current Part 820

Supplemental Provisions

§820.35: Control of Records*

- Signature and date requirements for records
- Information required by 21 CFR Part 803, complaint and servicing activities
- Documentation required to meet Unique Device Identification (UDI) requirements of 21 CFR Part 830
- Confidentiality of records FDA receives

Must meet these requirements in addition to those in Clause 4.2.5

§820.45: Controls for Device Labeling and Packaging*

- Proposes to retain requirements from QS reg as ISO 13485 fails to provide additional requirements
- ISO 13485 lacks requirements to address labeling inspection activities
- Intended to strengthen controls for labeling and packaging operations

Must meet these requirements in addition to those in Clause 7.5.1(e)

Proposed QMSR Key Considerations

- Incorporates the 2016 version of ISO 13485
  - Any future changes to the standard would need to be evaluated to determine impact to the rule and, if necessary, addressed through rulemaking
- Standard Availability: standard available in the ANSI Incorporated by Reference (IBR) Portal
  - ➢ https://ibr.ansi.org/
- Transition period
- FDA will retain its inspectional authority
  - FDA inspections will not result in the issuance of certificates of conformance to ISO 13485:2016
  - Manufacturers with a certificate of conformance to ISO 13485:2016 are not exempt from FDA inspections
  - FDA will not **require** ISO 13485 certificates

FDA Implementation Activities

- Updating technology systems
- Training of personnel
- Replace current inspection approach, Quality System Inspection Technique (QSIT)
- Revise [and/or develop] relevant regulations, policies, procedures and other documents impacted by this rulemaking
  - ✓Compliance Program Guidance Manual (CPGM)
  - ✓Guidance Documents
- Education and Communication

- Send any questions to Proposed-Device-QMSR-Rule@fda.hhs.gov


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