FDA U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR DEVICES & RADIOLOGICAL HEALTH

21 CFR 820 Amendment Proposed Rule Quality Management System Regulation

Keisha R. Thomas
Acting, Associate Director of Compliance and Quality
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

Similarities and Differences

Similarities

- By far outweigh the differences
- Substantively similar requirements, when taken in totality
  - Intent
  - Scope: substance fundamentally unchanged
  - Requirements

Differences

- To ensure that the incorporation by reference of ISO 13485 does not create inconsistencies with other applicable FDA requirements
  - Title
  - Definitions
  - Clarification of Concepts
  - Requirements
    - Risk Management
    - Supplementary Provisions: FDA-specific
    - Linkages/ Applicable Regulatory Requirements
    - Conforming Amendments

Similarities

Substantively similar requirements, when taken in totality

- Intent
- Scope: substance fundamentally unchanged
- Risk Management (Expectations)
  - FDA has expected risk management throughout a QMS and the total product lifecycle, though only listed specifically as a requirement in §820.30g
  - Expected explained through preamble comments

FDA expects *risk management* activities to begin early in the design and development process and be integrated throughout a manufacturer's Quality Management System.

		Preamble Comment
820.1	Scope	4, 13
820.30	Design Controls	81, 83
820.50	Purchasing Controls	99, 115
820.65	Traceability	121
820.70	Production and Process Controls	31
820.90	Nonconforming Products	161
820.100	Corrective and Preventive Action (CAPA)	159
820.200	Servicing	200

Differences

To ensure that the incorporation by reference of ISO 13485 does not create inconsistencies with other applicable FDA requirements

- Title
- Definitions
- Clarification of Concepts
- Requirements
  - Risk Management (Requirements)
    - Perceived differences with explicitly integrated requirements
  - Supplementary Provisions (FDA-specific)
  - Linkages/ Applicable Regulatory Requirements

Definitions

1. Withdrawing: do not have a corollary in ISO 13485 because they are not needed to understand and implement the proposed part 820

- Establish

2. Retaining: terms that do not appear in ISO 13485, but are necessary for the purposes of part 820 and are necessary to ensure alignment with the FD&C Act and its implementing regulations

- Act (expanded to add Federal Food, Drug, and Cosmetic to the term)
- Management with executive responsibility*:* retaining current definition from the QS regulation, but replacing it with the term '*top management*'
- Validation of processes: retaining the definition of process validation from the QS reg and recognizing as synonymous with the term *validation of processes*
- Retaining without change the definitions for component; finished device; human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device; design validation; remanufacturer; nonconformity; verification
- Manufacturer: retaining current definition because it is more comprehensive

3. Adding

- Customer

Definitions

4. Clarify/Supersede: terms that are defined in ISO 13485, which we propose not to incorporate and are proposing definitions that supersede the definition of the similar term in the standard

- Device: superseding '*medical device'* in ISO 13485
- Labeling: superseding *'labelling'* in ISO 13485

5. Retain with modification

- Rework*:* removing the term device master record (DMR), since it is not referenced in ISO 13485
- Product: retaining from the QS reg, but adding '*service*' to the definition

Clarification of Concepts

Organization

- Clarify the term to also include 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

Requirements

Risk Management*

- Greater emphasis on risk management activities
  - Explicit integration of risk management throughout the requirements
  - Establishes a requirement for risk management to occur throughout the total product lifecycle

**Not to be perceived as new requirements*

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

Supplementary Provisions

FDA-specific

- 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

Supplementary Provisions

FDA-specific con't

- 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)

Linkages/Applicable Regulatory Requirements

Requirement to comply with other linked 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)

Conforming Amendments

Amend part 4 to reflect the amendments to part 820 in incorporating ISO 13485:

- Not proposing to change the underlying activities required
- Does not impact the cGMP requirements for combination products
- Proposing amendments to the part 4 references to the corresponding clauses in ISO 13485

Summary

- Requirements substantially similar
  - Provides similar level of assurance
- Changes to align with statutory or applicable regulatory requirements
- Soliciting comments on proposed regulatory requirements, amendments, impact


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