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FDA's Transition to the Quality Management System Regulation

Update on Proposed Rule aligning the 21 CFR Part 820 with ISO 13485:2016

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

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Speaker Introduction

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Update on Proposed Rule aligning the 21 CFR Part 820 with ISO 13485:2016

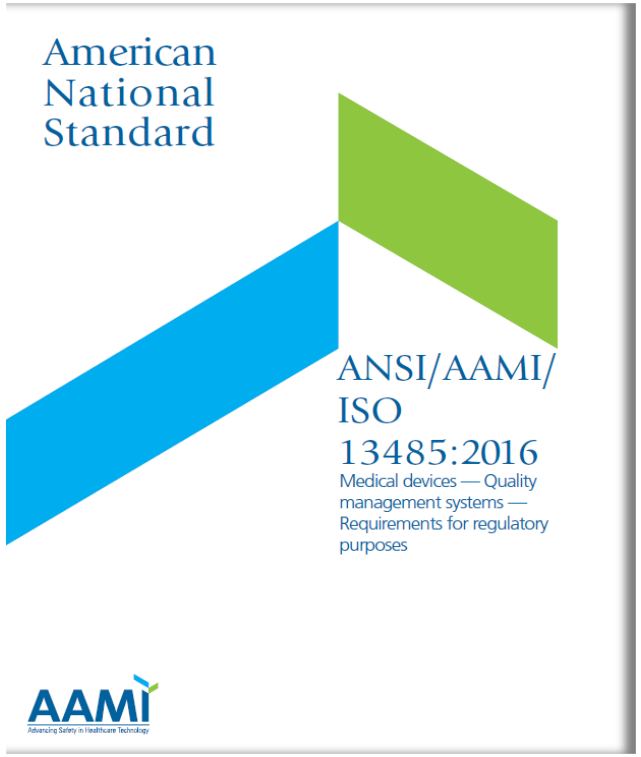
Keisha Thomas & Karen Masley-Joseph

Proposed Rule: 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.

Rationale for Utilization of ISO 13485: 2016

- Modernized QMS principles
- Greater integration of risk management activities
- Globally harmonized requirements
  - Standard used by many other Regulatory Authorities
  - Many global manufacturers already comply with ISO 13485
  - Requirements are substantively similar between the current part 820 and ISO 13485:2016



Goals of the Proposed Quality Management System Regulation

- Simplify and Streamline the Regulation
- Reduce burden on manufacturers
- Keep country specific requirements at a minimum
- Maintain a similar level of assurance in a manufacturer's quality management system

Overview of the Proposed Quality Management System Regulation

- Withdraws most of the requirements in the current part 820
  - Retains the scope and a number of the definitions from the current part 820
- 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

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/Standards/iso.aspx
- 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 personnel
- Replace Quality System Inspection Technique (QSIT)
- Revise (and/or develop) relevant regulations, policies, procedures and other documents impacted by this rulemaking
  - Compliance Program updates
  - Guidance Document updates
- Communication

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

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Questions & Discussion

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Closing Remarks

Summary and References

- FDA published the proposed amendment to 21 CFR Part 820: Medical Devices; Quality System Regulation Amendments, on February 23, 2022.
- Revisions to Part 820 replace most of the existing regulation with an incorporation by reference to ISO:13485:2016.
- Send questions to Proposed-Device-QMSR-Rule@fda.hhs.gov
- Reference to FDA FAQs?
  - https://www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/proposed-rule-quality-system-regulation-amendments-frequently-asked-questions