

FDA

**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES & RADIOLOGICAL HEALTH

FDA

**Overview:
21 CFR 820 Amendment
Proposed Rule
Quality Management System
Regulation**

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Proposed Quality Management System Regulation (QMSR)



FDA/CDRH is proposing to harmonize the current Quality System (QS) regulation for medical devices (21 CFR 820) by converging its requirements with requirements used by many other regulatory authorities

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 requirements in ISO 13485:2016, when taken in totality, are substantially similar to the current requirements of Part 820, QS regulation



ISO 13485: 2016

Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

Establishes requirements for a Quality Management System (QMS) that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including:

- design and development
- production
- storage
- distribution
- installation
- servicing and
- final decommissioning/disposal of medical devices

American
National
Standard



ANSI/AAMI/
ISO
13485:2016
Medical devices — Quality
management systems —
Requirements for regulatory
purposes

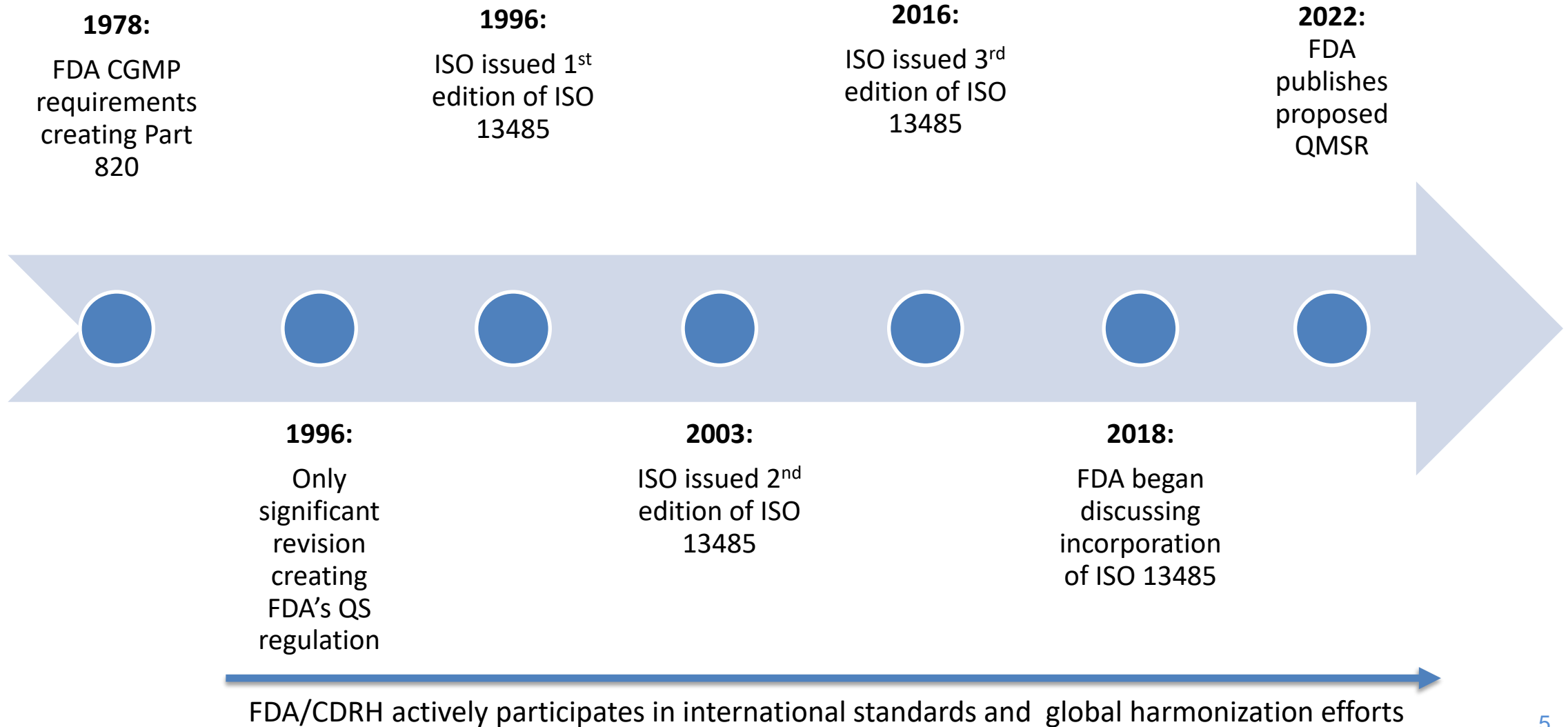


Benefits of ISO 13485: 2016



- The standard has
 - Modernized QMS principles
 - Greater integration of risk management activities and stronger ties to ISO 14971 than the QS regulation
 - Globally harmonized requirements

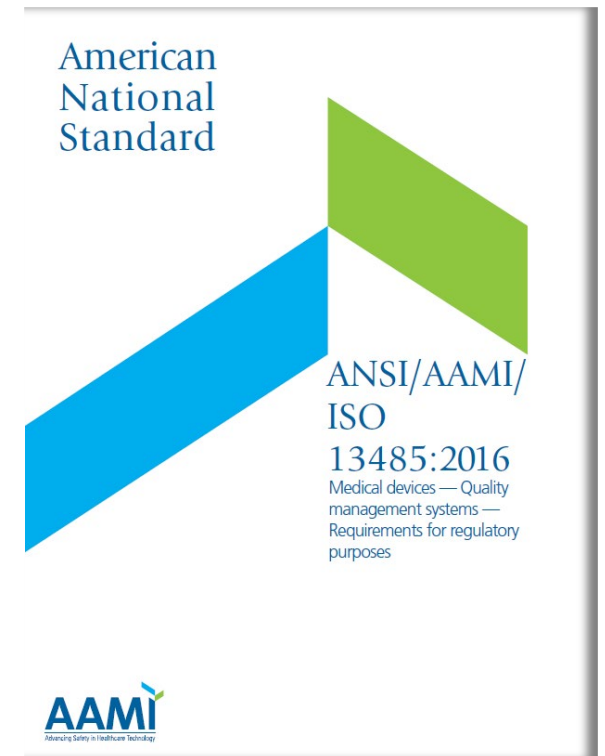
Evolution of QMS Requirements for Medical Devices



Rationale for FDA's Utilization of ISO 13485: 2016



- Regulatory expectations for a QMS have evolved since the current part 820 was implemented 25 years ago
- ISO 13485:2016 is already used by regulatory authorities in many other countries as basis for QMS requirements
 - Many global manufacturers already comply with the requirements of ISO 13485
- Requirements, when taken in totality, are substantively similar between the current part 820 and ISO 13485:2016
- Lessons learned through current and previous FDA programs utilizing ISO 13485 demonstrated feasibility





FDA's Interest in ISO 13485

- FDA has actively engaged in global harmonization efforts and standards development processes including the development of the different versions of ISO 13485
- FDA has always had an interest in seeking ways to harmonize requirements with ISO 13485 including programs such as:
 - Pilot Multi-Purpose Audit Program (PMAP)*
 - ISO 13485 Voluntary Audit Report Submission Pilot Program*
 - Medical Device Single Audit Program (MDSAP)

Pilot Multi-Purpose Audit Program



September 2006

- Auditing organizations performed an audit of a medical device manufacturer to satisfy requirements at the time of both Health Canada (ISO 13485:2003) and US FDA (21 CFR 820, 803, 806)
- Health Canada and US FDA used the experience gained with the PMAP to identify best practices and to promote an enhanced cooperative regulatory approach
 - Increased awareness of the advantages of multipurpose audits/inspections
 - Demonstrated regulatory cooperation between Canada and the US
 - Led to a reduction of regulatory burden on industry
 - Early lessons learned were incorporated into the development of MDSAP
 - Demonstrated the similarities between QMS requirements

ISO 13485 Voluntary Audit Report Submission Pilot Program

March 2012

- Accepted ISO 13485:2003 audit reports in lieu of routine FDA surveillance inspections
 - Precursor to MDSAP
 - No longer active program because MDSAP is now in full implementation
- Reasons for the program:
 - ISO 13485 audits are performed domestically and internationally
 - More efficient use of FDA inspectional resources
 - Harmonization with other countries
 - Demonstrated similarities in ISO 13485 requirements and the QS regulation

Guidance for Industry, Third Parties and Food and Drug Administration Staff

Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

Document issued on: March 19, 2012

The draft of this document was issued on May 20, 2010.

OMB control number: 0910-0700

Expiration Date: 02/28/2015

See additional PRA statement at the end of this guidance

For questions regarding this document, contact Kimberly A. Trautman (CDRH) at 301-796-5515 or by email at Kimberly.Trautman@fda.hhs.gov, or the Center for Biologics Evaluation and Research (CBER), the Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709 or 301-827-1800 or ocod@fda.hhs.gov.

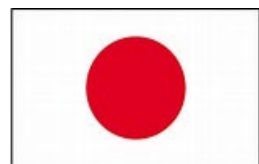
U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research



Medical Device Single Audit Program (MDSAP)



- MDSAP mission is to “...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers”
- Allows recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of participating Regulatory Authorities (Australia, Brazil, Canada, Japan, and the US)
 - Utilizes ISO 13485: 2016 as base QMS requirements plus specific jurisdictional requirements incorporated into the audit model
 - Lessons learned through program helped set the stage for proposed QMSR

Goals of the Proposed Quality Management System Regulation



- Simplify and streamline the regulation
- Reduce burden on manufacturers by aligning FDA's requirements with globally harmonized QMS requirements
- Incorporate ISO 13485:2016 while keeping country specific requirements at a minimum
 - Only add in requirements necessary to remain in alignment with FD&C Act
- Maintain a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective

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

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.



Structure of the Proposed QMSR

820.1 Scope.

820.3 Definitions.

820.7 Incorporation by reference.

820.10 Requirements for a quality management system.

Links additional FDA requirements such as MDR, UDI, Corrections & Removals, and Tracking; applicability of Design and Development activities

820.15 Clarification of concepts.

Correlates concepts in ISO 13485 to FDA

820.35 Control of records.

Supplements record keeping activities: signature and date, complaint/servicing records, UDI, and confidentiality

820.45 Device labeling and packaging controls.



Proposed QMSR Key Considerations

- Does not modify which establishments or products are subject to part 820
- 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
- Proposes a transition period of one year after publication of final rule
- ISO 13485: 2016 standard available in the ANSI Incorporated by Reference (IBR) Portal
 - <https://ibr.ansi.org/>
- FDA will retain our 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 Implementation Activities



- Updating technology systems
- Training of personnel
- Replacing the current inspection approach (Quality System Inspection Technique (QSIT)) with a new inspection approach consistent with the requirements of the rule when finalized
- Revising relevant regulations and other documents impacted by this rulemaking

