The Quality Management System Regulation (QMSR): Implications for Manufacturers of Medical Devices

Anne Holland
CEO and Founder
QA Consulting, Inc.
Qaconsultinginc.com

QA CONSULTING

October 2024

Executive Summary

The recent finalization of the Food and Drug Administration's (FDA) Quality Management System Regulation (QMSR) marks a significant long-awaited change for medical device manufacturers, effective 02 Feb 2026. The new 21 CFR Part 820 incorporates ISO 13485 *Medical devices-Quality management systems-Requirements for regulatory purposes* Third Edition, 2016-03-01 by reference. Clause 3 of ISO 9000:2015 Terms and Definitions are also incorporated by reference. The new 21 CFR Part 820 (2024), known as Quality Management System Regulation (QMSR) applies to an organization involved in one or more stages of the life cycle of a medical device. Some primary goals of the new QMSR are:

- **Simplify and streamline the current Quality System Regulation (QSR) by alignment with International Standards**. Where possible, definitions from ISO 13485:2016 as well as ISO 9000 Clause 3, were incorporated without modification from their originating standard or creating a new requirement to 21 CFR Part 820 regulation. The new 21 CFR Part 820 (2024) is harmonized to "align more closely with the international consensus standards for devices by converging with the QMSR requirements used by other regulatory authorities."[1] Harmonization with ISO 13485 and ISO 14971:2019 Medical Devices—Application of Risk Management by reference facilitates global market access for US-made devices and reduces the regulatory burden overall.
- **Enhanced Transparency**. The QMSR removes exceptions that previously shielded FDA inspection of internal audits 21 CFR §820.22, supplier evaluation audits 21 CFR §820.50(a) and management reviews 21 CFR §820.20(c) from FDA scrutiny. This fosters a culture of continuous improvement and harmonizes and strengthens regulatory oversight.
- **Lessen the burden.** QMSR imposes no requirement to obtain certification to ISO 13485, nor will FDA rely on such certification for the conduct of its oversight activities.
- **Clarify cGMP Requirements**. Include conforming edits to 21 CFR Part 4 (cGMPs) for combination products without impacting the cGMP requirements.

This white paper explores the key changes introduced by the QMSR and their potential impact on manufacturers of medical devices, and why the QMSR presents both opportunities and challenges for this market.

[1] Federal Register /Vol.89, No.23/Friday, Feb 2, 2024/Rules and Regulations, Summary p.7496.

Background

Everyone in the medical device community has likely heard that the FDA has incorporated by reference ISO 13485:2016 and definitions from ISO 9000:2015 Clause 3. The new 21 CFR part 820 title was changed from the Quality System (QS) regulation to the Quality Management System Regulation (QMSR) to differentiate the1996 version of the regulation from the 2024 regulation.

The QMSR was promulgated on 02 Feb 2024 with a two-year implementation period. As of 2 Feb 2026, the FDA Inspections will immediately shift to the new QMSR. The belief that if one is already after us ISO 13485:2016 certified or complying with 21 CFR 820 QS requirements, then there is not significant work to be done for compliance to the QMSR may not be advisable. For best results with implementation, be careful to review and understand the preamble where the background, logic and rationales for responses are located.

The Food and Drug Administration (FDA) is issuing a final rule to amend the US 21 CFR part 820 (cGMP) current good manufacturing practice (cGMP) requirements of the Quality System regulation (QS) to harmonize and modernize the regulation. The FDA is harmonizing to align more closely with the international consensus standards for devices by converging with the Quality Management System (QS) requirements used by other regulatory authorities from other jurisdictions (i.e., other countries). The FDA is doing so by incorporating by reference international standards specific for medical device quality management systems.

It is important to understand that if a conflict exists between the FDA QMSR per the FD&C Act and ISO 13485, the FDA regulation will have priority. Examples include the definition of medical device and labelling.

Through this rulemaking, additional requirements are also established and conforming edits to the QMSR are made to clarify the device cGMP requirements. Once effective, the new QMSR will more closely align the FDA's regulatory framework with that used by regulatory authorities in other jurisdictions to promote global harmonization of medical device regulation and provide timelier introduction of safe, effective, high-quality devices for patients while removing duplicative requirements and market barriers that lead to inefficiencies and increased costs.

Key Changes and their Impact

While the core quality management principles remain, the QMSR introduces several key changes with specific implications on device manufacturers who perform one or more stages of the life cycle of a medical device (reference Table 1).

Table 1 ISO 13485 Life Cycle Stages

Design and development
Production
Storage
Distribution
Installation
Servicing
Final decommissioning/ disposal of medical devices

Key Changes:

Terminology: The QMSR adopts ISO 13485 terminology, replacing the "Device Master Record" (DMR), Device History Record (DHR) and DHF with the broader concept of a "Medical Device File." The recordkeeping requirements in ISO 13485 are substantively similar to those in the QSR and therefore there is no need for redundant terminology. Also, the FDA has clarified the "safety and performance" as stated in ISO 13485 is equivalent to the term "safety and effectiveness" in the FD&C Act.

Focus on Risk Management: The QMSR emphasizes a more proactive approach to risk management, requiring manufacturers to identify and mitigate potential risks throughout the entire device life cycle. This enhanced focus on risk improves quality consistency and patient safety for all device classes.

Additional Requirements: "The requirements enumerated in the new 21 CFR § 820.10 (b)(1) through (3) make explicit that compliance with other parts of Title 21 is central to a comprehensive QMS system." Manufacturers must establish and maintain a QMS and comply, as appropriate, with other "applicable regulatory requirements" such as UDI per 21 CFR part 830, identification and traceability per 21 CFR part 821, reporting to regulatory authorities per 21 CFR part 803 and advisory notices in accordance with 21CFR part 8062. These requirements are critical to a comprehensive QMS system however the list is not all inclusive.

[2] New 21 CFR §§ 820.10(b) & (d)

Design Controls: The scope of design controls will remain the same as in the current QS, which applies to selected class I devices as well as class II and class III finished devices. Design controls also apply to human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated as devices. Design controls will continue to apply to manufacturers of finished devices; however, FDA retains the authority to extend the rule to components or parts if necessary. As is currently the case, design controls will not apply to early-stage research. Once design inputs are approved, are approved design changes apply. [Comment 45]

Software Validation: 21 CFR § 820.30(g) will no longer refer to software validation. The new QSMR defines that "product realization "applies to both hardware and software as the preamble defines a component to mean any raw material, substance, piece part, software, firmware, labeling or assembly that is intended to be included as part of the finished, packaged, and labeled device."

"Correction" in Addition to "Corrective Action": The QMSR clarifies the distinction between immediate actions to address a non-conformance ("correction") and systemic changes to prevent recurrence ("corrective action"). This distinction ensures a comprehensive approach to addressing quality issues. [Comment 29]

Potential Challenges and Considerations

While the QMSR offers benefits, some device manufacturers may face challenges:

Compliance Costs: Implementation of new processes and documentation may require adjustments to existing workflows and potentially incur additional costs.

Shifting Focus: A stronger emphasis on risk management throughout the lifetime of the device may necessitate a cultural shift within an organization accustomed to a less-intensive approach of risk management.

MDSAP and ISO 13485 Certificates will not be accepted in lieu of an FDA Inspection. Furthermore, the FDA is planning to update its Guide to Inspections of Quality Systems (QSIT), however the approach to be taken is yet unknown.

Implementation of the QMSR could pose a burden on U.S. manufacturers without prior ISO 13485 experience. Although 21 CFR part 820 and ISO 13485 are "substantially similar". Even seemingly small changes require careful planning and implementation.

Strategies for Effective Implementation

Device manufacturers can successfully navigate the QMSR by adopting proactive strategies.

Gap Analyses and Planning: A thorough analysis of existing quality systems against the QMSR requirements, followed by a well-defined implementation plan with timelines and resource allocation, is crucial for a smooth transition.

Risk Management Integration: Embedding a robust risk-based approach throughout the device lifecycle, from design and development to production with links to post-market surveillance, ensures proactive identification and mitigation of potential risks.

Documentation and Training: Updating documentation to reflect the new terminology and providing comprehensive training for personnel on QMSR-specific requirements and best practices are essential for successful implementation.

Lean Into QA Consulting to facilitate full transition to QMSR Compliance.

FDA Frequently Asked Questions and Preamble

In my experience, the most interesting part of the new QMSR is within the preamble as was true with the prior QS: Less than 100 comments were filed. Preambles are notes that provide detailed information about the rule's background, purpose, and justification. They can also include the FDA's interpretation of the rule's meaning and impact, as well as any public comments received and the FDA's response to those comments. Thus, the preamble contains valuable insight into the meaning and intent of the QSR.

In the preamble, many comments made general remarks supporting the proposed rule without focusing on a particular provision. Many comments agreed with FDA's goal to harmonize the QMSR with an internationally recognized standard. Multiple commenters agreed with FDA that this rulemaking will streamline regulations regarding quality. Because the purpose of this rulemaking is both to harmonize with international standards, where possible, and to retain the scope of the QS regulation, and amending many provisions to clarify expectations and concepts used in ISO 13485.

1. **What is the FDA doing to prepare for harmonization of the Quality System regulation with ISO 13485?**

The FDA intends to engage in a variety of implementation activities including, updating information technology systems, training FDA staff responsible for assessing compliance with medical device quality management system requirements, developing an inspection process, revising relevant regulations and other documents impacted by this rulemaking, and communicating and educating stakeholders, including affected FDA staff, on the change.

2. **Do these changes apply to US Class I, II, and III medical devices?**

Yes, the changes in the FDA's Quality Management System Regulation (QMSR) apply to all classifications of medical devices, but with some specific considerations:

Class II and III Devices: These devices are generally subject to the full scope of design control requirements. The updated QMSR emphasizes risk management and aligns closely with ISO 13485 standards, which are already a requirement in many international markets

Class I Devices: While most Class I devices are exempt from design control provisions, there are exceptions. The QMSR maintains these exceptions, so the majority of Class I devices will not be subject to the full design controls required for higher-risk devices. However, some Class I devices that include software or specified devices such as surgeon's gloves fall into special controls and will need to comply with design control requirements. [Comment 45]

3. How does the QMSR Scope compare to QSR?

The final rule also clarifies that the QMSR has the same scope as the QS. The QMSR will apply to finished medical devices and certain human cell, tissue, and cellular and tissue-based products (HCT/Ps) regulated as devices. The new QMSR does not extend to component manufacturers, third-party servicers, or refurbishers, maintaining the existing scope of the previous Quality System Regulation (QS). The preamble does however point out that the FDA has the enforcement power to regulate components or third-party service providers if they choose. [Comment 2]

4. Will the FDA continue to Inspect Manufacturing Facilities?

While ISO 13485 certification is not mandatory, the QMSR's integration of its principles means that companies already compliant with ISO 13485 may find the transition smoother. However, the FDA will continue to conduct its own inspections and will not rely solely on ISO 13485 certifications for regulatory oversight. [Comment 79,80]

Summary

In summary, the QMSR changes apply broadly across all classes of medical devices, with specific provisions and exemptions detailed for different classes. Manufacturers should review the final rule and preamble to understand the specific requirements for their products.

This rulemaking is intended to develop and use standards published by the FDA and International Organizations for Standards. The QMSR is intended to converge and harmonize international medical device standards, and it is consistent with the least burdensome principles stated in the FDA Agency's guidance document[3] Harmonizing FDA regulations with the ISO standards will have benefits for manufacturers because many firms producing devices for sale within the United States and abroad must already comply with both standards. This rule will require compliance with more closely aligned requirements and although the FDA will maintain their inspections, the new QMSR may decrease the overall quantity of supplier audits due to reliance on increased medical diligence. FDA notes that harmonizing the regulation of devices will help provide safe, effective, and high-quality devices, contributing to public health through timelier access for patients. FDA agrees that harmonizing regulations from different regulatory jurisdictions will remove unnecessary duplicative regulatory requirements.

Lean Into QA Consulting to Facilitate Customized Full Transition to QMSR Compliance.

[3] The Least Burdensome Provisions: Concept and Principles, Guidance for Industry and Food and Drug Administration Staff, Issued 5 Feb 2019