Preparing for the FDA's Quality Management System Regulation (QMSR)

A practical guide for medical device firms

THE FDA GROUP LLC

Table of Contents

3 A Brief Introduction to the QMSR

6 What's Inside the QMSR?

15 A Word About Risk Management

16 The QMSR's Impact on Medical Device Manufacturers in the United States

17 QMSR Inspection Considerations

18 A Few QMSR FAQs

19 Next Steps for QMSR Transition

22 How The FDA Group Can Support Your QMSR Transition

A Brief Introduction to the QMSR

On February 2, 2024, the FDA ***issued a final rule*** that modifies the device good manufacturing practice (GMP) requirements of the Quality System Regulation (QSR) and harmonizes them with ISO 13485:2016, which is a set of internationally recognized standards.

The final rule also changes the name of the FDA's QSR to "Quality Management System Regulation" (QMSR). This move aligns the regulatory requirements for medical devices in the United States with ISO 13485:2016, which is already harmonized in the European Union under the EU Medical Device Regulation (EU MDR).

The QMSR will come into effect on February 2, 2026. Until this date, firms are expected to continue complying with the existing QSR. This transition period has been extended from the proposed one-year transition period in response to industry feedback, highlighting the need for more time to update QMSs. Suggestions for alternatives, such as different transition periods for small and large companies or phased transitions, were considered but ultimately rejected by the FDA. During this transition period, the FDA will be working on updating guidance documents, revising its inspection guide, and providing staff training.

In early 2018, the FDA announced a proposed rule to align U.S. regulatory requirements with ISO 13485. On February 23, 2022, the FDA published the proposed rule, recognizing the need to update the QSR, which had not been significantly revised since 1996. The agency adopted ISO 13485 to form the core of the new QMSR.

The new regulation aims to align with the international standard and supports the FDA's objective of promoting international regulatory harmonization while reducing redundancy in requirements for global manufacturers. The FDA has been involved in establishing and maintaining ISO 13485 since its inception in 1996 and has been working towards bringing QSR and the ISO standard further into alignment with each revision.

Between February 23, 2022, and May 24, 2022, the FDA received 83 categories of comments in response to the proposed rule. In the preamble to the QMSR final rule, the agency addresses these comments and notes that "almost all comments voice support for the objective of the proposed rule, to update and modernize the CGMP requirements of the QS regulations by incorporating ISO 13485."

The transition to the new QMSR incorporating ISO 13485:2016 has several implications for medical device manufacturers. Here they are at a glance:

- **(Mostly) Minimal Overhaul:** ISO 13485:2016 and QSR requirements are similar, so a complete QMS should not be necessary for most impacted firms.
- **Combination Products:** 21 CFR Part 4 will be amended to clarify QMS requirements for combination products, though CGMP requirements remain unchanged.
- **Inspection Changes:** The FDA plans to update its inspection process to align with QMSR requirements, but details are pending.
- **ISO 13485 Certification:** Having this certification doesn't guarantee QMSR compliance or exempt manufacturers from FDA inspections.
- **New Focus Areas:** Manufacturers should familiarize themselves with new QMSR sections and plan for compliance, even if already conforming to ISO 13485:2016.
- **Potential Simplification:** The transition aims to streamline regulatory processes and reduce burdens on manufacturers. The work required to transition should pay a long-term dividend in this regard.

This guide describes the final rule's structure and content and highlights its differences from the proposed rule. Additionally, we offer insights on how the new QMSR will impact the industry and the FDA.

In addition to this white paper, we recommend reviewing the following resources:

- ***Quality Management System Regulation: Final Rule Amending the Quality System Regulation – Frequently Asked Questions***
- ***Medical Devices; Quality System Regulation Amendments (Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis)***
- ***Proposed Rule Medical Devices; Quality System Regulation Amendments – 21 CFR 820 (Presentation Slides)***
- ***Summary Minutes: CDRH Devices Good Manufacturing Device Panel – March 2, 2022***

Need expert QMSR transition support? We can help.

Many impacted firms will require outside specialists to plan and execute their compliance strategy effectively. The primary consultant should be a seasoned QMS expert with extensive experience in both FDA QSR and ISO 13485:2016 standards to lead a gap analysis, implement risk management components where necessary, implement changes, and train on them.

Here at The FDA Group, we have an extensive consulting network perfectly positioned to help you navigate the evolving QMS landscape efficiently while ensuring compliance through:

- **Gap Assessments:** We conduct thorough gap assessments against ISO 13485:2016 and the FDA's QMSR, identifying areas of non-conformance and opportunities for improvement.
- **QMS Transition Planning:** We assist in developing a comprehensive transition plan for the QMSR, addressing and resolving any gaps identified during the gap assessment phase.
- **Inspection Preparedness:** We offer audits and mock inspections tailored to your QMS based on applicable standards and regulations to ensure readiness for actual regulatory inspections.
- **Risk Management Enhancements:** We evaluate and assess your existing risk management procedures, plans, reports, and records. We can also assist in the development and implementation of comprehensive risk analyses, plans, and reports to strengthen this critical aspect of your QMS.
- **Supplier Quality Management:** We conduct quality audits of your suppliers to ensure their compliance with relevant standards and regulations, thereby ensuring the integrity of your supply chain.

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What's Inside the QMSR?

The QMSR is a concise document (just a few pages long). Most of the existing 21 CFR Part 820, the QSR, is replaced with entirely new sections under the new QMSR. While many changes are primarily semantic, some substantive modifications will affect medical device companies.

For example:

- **Terminology Shifts:** Terms like Device Master Record (DMR), Design History File (DHF), and Device History Record (DHR) are replaced by the broader "Medical Device File" (MDF) concept from ISO 13485. However, the documentation requirements these terms represent remain intact.
- **Definition Precedence:** FDA definitions will supersede ISO 13485 definitions where inconsistencies exist (e.g., 'device' vs. 'medical device', 'labeling' vs. 'labelling').
- **New Sections in Part 820:**
  - 820.7: Incorporation by reference
  - 820.10: Requirements for a quality management system
  - 820.35: Control of records
  - 820.45: Device labeling and packaging controls
- **Enhanced Labeling and Packaging Requirements:** Section 820.45 introduces more stringent controls, addressing a common cause of device recalls. Essential requirements include procedures for UDI/UPC, expiration dates, storage instructions, handling instructions, and processing instructions. These are in addition to existing 21 CFR Part 801 labeling requirements.

Here's a high-level look at the changes to the QSR made by the QMSR as summarized by the FDA:]

21 CFR Part 820–Quality Management System Regulation

Subpart A: General Provisions

820.1	Scope
820.3	Definitions
820.5	(Reserved from QSR)
820.7	Incorporation by Reference
820.10	Requirements for a Quality System

Subpart B: Supplement Provisions

820.20 - 820.30	(Reserved from QSR)
820.35	Control of Records
820.40	(Reserved from QSR)
820.45	Device Labeling and Packaging

Subparts C through O are reserved from the QSR

We discuss particular areas of interest below.

Section 820.1 (Scope)

The new QMSR's scope remains practically identical to the current QSR. The new QMSR covers finished devices and human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated as devices. However, components and parts of finished devices and blood and blood components are not included. It's important to note that although components or parts of finished devices are not part of the scope, the FDA has the authority to extend the rule to those components or parts should it be necessary.

The QMSR applies to manufacturers, contract sterilizers, installers, relabelers, remanufacturers, repackers, specification developers, and initial distributors of foreign manufacturers. Additionally, component manufacturers are encouraged to voluntarily comply with the QMSR. This particular section of the QMSR outlines the guidelines for manufacturers to resolve conflicts between the FD&C Act and its implementing regulations, and ISO 13485.

It's crucial to note that in case of any conflict with ISO 13485, the FD&C Act and FDA regulations will have priority. The FDA has given two examples of such conflicts in the preamble:

- the definitions of "device" and "labeling" in the FD&C Act are more authoritative than the definitions of "medical device" and "labelling" in ISO 13485; and
- it's clarified that the term "safety and performance" in ISO 13485 is equivalent to the term "safety and effectiveness" in the FD&C Act.

A few key action items:

- **Review and Update Scope Understanding:** Ensure your organization's understanding of the QMSR's scope aligns with the final rule, covering finished devices and HCT/Ps regulated as devices.
- **Assess and Prepare for Potential Expansion:** If necessary, the FDA may extend the rule to components or parts of finished devices.
- **Voluntary Compliance for Component Manufacturers:** To align with industry standards and expectations, component manufacturers should consider voluntarily complying with the QMSR.

Section 820.3 (Definitions)

The definitions listed in ISO 13485 are generally suitable per the FDA. For terms and definitions that don't align with or are not in ISO 13485, the FDA retained, modified or further clarified terms in the QMSR and removed all correlating terms.

The following is a list of the terms and definitions listed in 820.3 of QMSR:

- "Component"
- "Federal Food, Drug, and Cosmetic Act"
- "Finished Device"
- "Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device"
- "Implementable Medical Device"
- "Remanufacturer"
- "Manufacturer"
- "Organization"
- "Rework"
- "Safety and Performance"

Note that within ISO 13485, there is one Normative Reference to ISO 9000:2015, "Quality System Management Systems – Fundamentals and Vocabulary." The FDA considers terms and definitions in ISO 9000, as used in ISO 13485, to be incorporated by reference into the QMSR.

ISO 13485 only references the terms and definitions in Clause 3 of ISO 9000, which are being incorporated by reference. It does not reference the remainder of the document. The FDA considers the remainder of ISO 9000 to fall outside the scope of the QMSR. Please keep this in mind when referring to ISO 13485 and ISO 9000 for applicable definitions.

The FDA had to make several adjustments to regulatory definitions as a result of incorporating ISO 9000 terms and definitions in the final rule:

- The FDA has removed definitions for several terms from the proposed rule, opting instead for the corresponding definitions and concepts found in ISO 9000 and ISO 13485. These terms include "customer," "design validation," "non-conformity," "process validation," "product," and "verification." Additionally, "top management" in ISO standards replaces the QSR's term "management with executive responsibility."
- The industry resisted the FDA's replacement of the QSR term "establish" with the ISO 13485 term "document" in the proposed rule. The FDA acknowledged the slight differences in definitions but argued that the terms are close enough that separate definitions would be redundant.

- A significant change in definitions includes the elimination of the QSR terms "Design History File" (DHF), "Device Master Record" (DMR), and "Device History Record" (DHR). The FDA clarified that ISO 13485 effectively requires firms to maintain these records but under different names: design and development files, Medical Device Files, and medical device or batch records.
- ISO 13485 incorporates the definition of "risk" from ISO 14971, which is focused on the probability and severity of harm. While the FDA does not adopt ISO 14971 in this rulemaking, it acknowledges that ISO 13485's conception of risk includes safety or performance requirements and applicable regulatory compliance. This approach encourages manufacturers to integrate regulatory compliance risk into their safety risk management processes.
- The final rule maintains the FD&C Act definitions of "device" and "labeling," which precede those in ISO 13485. Similarly, the definition of "manufacturer" in the QMSR supersedes the ISO standard definition, aligning with the QSR definition.

A few key action items:

- **Update Your Definitions:** Update your QMS documentation to reflect the new and adjusted definitions from ISO 9000 and ISO 13485, ensuring consistency with the QMSR.
- **Reevaluate "Establish" vs. "Document":** Understand the alignment between the terms "establish" and "document" in your QMS procedures and records.
- **Align Risk Management:** Integrate regulatory compliance risk into your safety risk management processes, acknowledging the broader definition of "risk," incorporating safety, performance, and regulatory compliance.

Section 820.10 (Requirements for a Quality Management System)

This section of the QMSR final rule incorporates ISO 13485 Quality System requirements while maintaining additional FDA medical device-related regulatory requirements.

- **Clause 7.5.8. Identification:** Unique Device Identification requirements are provided (21 CFR Part 830, Unique Device Identification).
- **Clause 7.5.9 Traceability:** Traceability/Medical Device Tracking is provided (21 CFR Part 821, Medical Device Tracking).
- **Clause 8.2.3 Reporting to Regulatory Authorities:** FDA MDR requirements are provided (21 CFR Part 803, Medical Device Reporting).
- **Clause 7.2.3 Communication, 8.2.3 Reporting to Regulatory Authorities, and 8.3.3 Actions in Response to Nonconforming Product Detected After Delivery:** FDA Advisory Notices requirements have been included (21 CFR Part 806, Corrections and Removals).

This section specifies the devices subject to the design and development requirements of ISO 13485 (clause 7.3). These requirements replace the design control requirements of QSR, which are outlined in 21 CFR Part 820.30.

The scope of the devices subjected to these requirements includes Class II and Class III devices, along with specific Class I devices. Note that this scope remains the same as outlined in the QSR. Furthermore, ISO 13485 (clause 7.5.9.2) provides traceability requirements for implantable devices. This QMSR section specifies that these traceability requirements extend to devices that support or sustain life.

Lastly, but very importantly, failure to comply with the requirements of the new QMSR found in the amended 21 CFR Part 820 (and, by extension, ISO 13485) renders a device adulterated.

A few key action items:

- **Implement ISO 13485 Requirements:** Ensure your QMS incorporates the ISO 13485 Quality System requirements, especially those not explicitly identified in ISO 13485 but necessary under FDA regulations (e.g., Unique Device Identification, Traceability, Reporting to Regulatory Authorities).
- **Consider Design and Development Requirements:** Verify that your devices subject to design and development requirements align with ISO 13485 (clause 7.3), replacing the design control requirements from the previous QSR.

Section 820.35 (Control of Records)

This section of the proposed rule initially stated that in addition to the requirements of Clause 4.2.5 in ISO 13485, the manufacturer must obtain the signature of each individual who approved or re-approved the record, along with the date of approval.

This statement caused anxiety for some commenters who argued that the proposed rule was more stringent and burdensome than the approval requirements of ISO 13485. In response, the FDA agreed and removed this requirement from the final rule. Therefore, the approval requirements for a particular record will be as defined in ISO 13485.

This section outlines specific content requirements for complaint records and service records. The final rule adds additional language that defines when a complaint investigation must be initiated, in line with the existing requirement in 21 CFR Part 820.198(c).

Specifically, complaints that involve the possible failure of a device, labeling, or packaging to meet any of its specifications must be investigated. The FDA also clarified how organizations should manage multiple complaint-handling units by emphasizing the importance of defining a corporate complaint-handling procedure to ensure consistency throughout different complaint-handling units and identifying a single group or unit responsible for coordinating all complaint-handling functions.

The FDA has recognized the differences between the QSR's corrective and preventive action CAPA requirements and the separate Corrective Action and Preventive Action requirements in the ISO standard. As a result, the agency has decided to align itself with the ISO standard.

The QMSR requires that complaints records include the corrections and corrective actions taken to address the complaint. Furthermore, the section also outlines Unique Device Identification (UDI) requirements in addition to those in the ISO standard. It also reminds manufacturers to mark their records as "confidential" to aid the FDA in determining what records may be disclosed to the public under 21 CFR Part 820.

A few key action items:

- **Adopt ISO 13485 Approval Requirements:** Align your record approval processes with ISO 13485's requirements.
- **Enhance Complaint and Service Record Procedures:** Implement procedures for initiating complaint investigations as specified, and ensure comprehensive management of complaint-handling units for consistency and coordination.

Section 820.45 (Device Labeling and Packaging Controls)

The FDA identifies a critical area in the Quality System where ISO 13485 falls short: overseeing the control and inspection of device labeling and packaging.

This concern is addressed in the QMSR because ISO 13485 lacks specific requirements for labeling and packaging and fails to address manufacturer labeling inspection. To remedy this, the QMSR mandates that manufacturers inspect device labels for accuracy against specific criteria before release, aligning with current regulatory requirements outlined in 21 CFR Part 820.120(b)e. For instance, the FDA highlights instances where medical device recalls occurred due to errors missed by automated readers. Therefore, the QMSR mandates that a person must physically examine a representative sample of labels before release, even if automated readers previously checked them.

A few key action items:

- **Inspect Device Labels Before Release:** Integrate a process for physical examination of a representative sample of device labels for accuracy before release, even if automated readers are used.
- **Align Labeling and Packaging Controls:** Ensure your QMS addresses the control and inspection of device labeling and packaging to fill gaps not covered by ISO 13485, according to QMSR mandates.

Other Important Points Regarding the QMSR

- **Effective Date Extension from Proposed Rule:** The transition time for implementing the new changes has been increased from one year to two years after they take effect. The start date for device manufacturers to comply is set for February 2, 2026. Until the new QMSR takes effect, manufacturers must continue to comply with the current QSR.
- **FDA Inspections Update:** We are awaiting further guidance from the FDA on inspections and updates to the QSIT guide. Very importantly, note that Management Review, Quality Audits, and Supplier Audits reports will be subject to FDA inspections, removing previous exemptions.

- **ISO Certification:** The FDA's inspections will not issue an ISO 13485 certificate. Additionally, holding an ISO 13485 certificate is neither required by the FDA for compliance nor accepted as proof of compliance.
- **Access to ISO Standards:** Device manufacturers can access read-only versions of ISO 13485:2016 and ISO 9000:2015 at no cost through the American National Standards Institute (ANSI). The links are available in the Supplementary Information section of the Final Rule.
- **Future Revisions of ISO Standards:** Should ISO 13485 and ISO 9000 undergo revisions, their impact will need assessment. The FDA will determine whether further amendments to the rule are necessary.
- **Requirement for Signatures and Dates:** ISO 13485:2016 does not specifically require signatures and dates on approvals. However, the FDA clarifies that the term "approved" implies that an approved document or record must bear a signature and date. This means that compliance with 21 CFR Part 11, which covers Electronic Records and Electronic Signatures, remains applicable for companies using electronic systems to manage documents, records, and electronic signatures.

A Word About Risk Management

Risk is mentioned repeatedly throughout ISO 13485, whereas in the current QSR, it is only mentioned in Design Controls (820.30). However, the FDA recognizes that the QSR's 1996 Final Rule covers Risk Management and Risk-Based decision-making, although it is not explicitly stated. This is mentioned in the preamble to the final rule. Therefore, it's reasonable to assume that transitioning to ISO 13485 should not pose any issues in this area. If you are a device manufacturer, please review your procedures to ensure that your processes address risk throughout the QMS and the entire lifecycle of your product.

There's been some discussion regarding direct expectations for compliance with ISO 14971. In the preamble to the final rule, the FDA explicitly states that it does not include ISO 14971, which deals with applying risk management to medical devices (2019), in the final QMSR rule.

However, there are two important considerations to note regarding this statement.

First, the FDA emphasizes elsewhere in the preamble that incorporating risk management throughout the product lifecycle, as outlined in ISO 13485, was a significant factor driving the development of the QMSR. Even though ISO 13485 doesn't mandate compliance with ISO 14971, it does reference this risk management standard as a valuable resource when establishing a risk management process.

Second, independent of the QMSR, the FDA has already recognized the 2019 revision of ISO 14971 as a consensus standard. This recognition doesn't mandate medical device firms to adhere to ISO 14971. Still, it does acknowledge that the FDA considers compliance with it as a means to fulfill regulatory requirements for risk management.

For these reasons, we recommend manufacturers incorporate ISO 14971 as part of their QMSR implementation program, considering its directional alignment with the FDA's perspective on risk management. At the very least, device manufacturers should ensure their processes adequately address risk management across the quality management system and throughout the entire product lifecycle.

The QMSR's Impact on Medical Device Manufacturers in the United States

There are a few very important points regarding the QMSR's impact on the device industry:

Minimal Impact for ISO 13485:2016 Certified or Aligned Companies

Businesses already certified or aligned with ISO 13485:2016 will encounter minimal adjustments due to the introduction of the QMSR. Their main tasks involve updating documents to reference the QMSR and making minor modifications to ensure complete compliance.

These companies, particularly those marketing devices in jurisdictions where ISO 13485 is the accepted GMP standard (such as the EU, Australia, Canada, and Japan), will likely see a reduction in both the complexity and cost of QMS compliance. However, they must revise procedures and work instructions to eliminate outdated QSR requirements and terminology references.

Somewhat Significant Impact for Companies Primarily Under QSR

Companies currently operating under the 21 CFR Part 820 QSR and not in compliance with ISO 13485 will face a significant overhaul. The transition to QMSR demands substantial updates to procedures and documentation to reconcile differences between the QSR and QMSR frameworks.

Notably, the QMSR emphasizes risk management and risk-based decision-making more strongly than the QSR. Adopting ISO 14971 for risk management practices is highly recommended to align with QMSR expectations. These firms must adapt their procedures to meet international standards while incorporating necessary provisions to remain compliant with the revised 21 CFR Part 820, including specific FDA requirements enhancing or clarifying ISO 13485 standards.

Additionally, the QMSR modifies 21 CFR Part 4 concerning the regulation of combination products by updating references from the QSR to relevant clauses in ISO 13485. This underscores the need for firms to thoroughly understand the QMSR, including the FDA's interpretations outlined in the rule's preamble, to effectively prepare for updates in quality management systems, inspection management, and regulatory compliance strategies. Contact us today to get the expert QMSR support you need.

QMSR Inspection Considerations

The FDA clarifies that introducing the QMSR will not change its inspection authority as defined in section 704 of the FD&C Act. However, the QMSR is expected to eventually replace the current ***Quality System Inspection Technique*** (QSIT), though specific details are not yet provided.

The agency also reaffirms that ISO 13485 certificates will not be issued after FDA inspections under the QMSR, and having an ISO 13485 certification does not exempt manufacturers from FDA inspections.

Participation in the MDSAP will still exempt manufacturers from routine FDA inspections. The FDA recognizes the need to assess the QMSR's effect on MDSAP but expects the program to become more harmonized and streamlined.

Concerning exemptions for management review materials, internal audits, and supplier audits from FDA inspections, the FDA states that such exemptions, previously noted in the QSR and QSIT, are not included in the QMSR. This change is due to these documents already being provided to notified bodies under ISO 13485 and MDSAP. The removal of this exemption aims to align global audit and inspection processes more closely.

A Few QMSR FAQs

We've answered a few burning questions below, sourced from the QMSR final rule.

→ *Why is the FDA harmonizing QSR and ISO 13485?*

The FDA points to several reasons:

- **Modernization:** The QSR has remained largely unchanged since 1996, while ISO 13485 has been regularly updated. This harmonization allows the FDA to align with current international QMS standards.
- **Global Alignment:** By incorporating ISO 13485, the FDA aims to explicitly require internationally recognized QMS expectations for devices under its jurisdiction.
- **Minimal Disruption:** The FDA believes the requirements in Part 820 and ISO 13485 are substantially similar, meaning the transition should not significantly increase compliance burdens for manufacturers.
- **Regulatory Simplification:** The harmonization is expected to streamline regulations, reduce industry burden, and potentially improve patient access to necessary devices.
- **Ongoing Relevance:** ISO standards are reviewed every five years, ensuring the incorporated standard remains current with industry best practices.

→ *Will the FDA accept ISO 13485 certifications in lieu of audits?*

No. The FDA will not directly accept ISO 13485 certifications as a substitute for audits. However, the FDA is a part of the MDSAP, which is based on ISO 13485. The FDA will review MDSAP audit reports but not merely accept the certification like Health Canada. Manufacturers must still modify their QMS to comply with ISO 13485 requirements, even if certification is not sought.

→ *What is the deadline for QMSR implementation?*

The rule becomes effective two years after its publication, with a mandatory compliance date set for February 2026. At this point, the FDA plans to cease QSR inspections and transition to the new inspection methodology.

→ *Will the QSR's inspection exemptions be retained?*

There are no more exemptions; the FDA can now inspect management reviews, internal audits, and supplier audit records. Manufacturers must ensure the completeness of their management review agendas, including risk management processes. The change was made because other regulatory jurisdictions have access to these records, and the FDA seeks the same level of access.

→ *Will the FDA use Medical Device Single Audit Program (MDSAP) audits as a substitute for routine FDA inspections?*

MDSAP is a voluntary certification program under which third-party auditing organizations audit participating medical device manufacturers according to core ISO 13485 requirements and additional country-specific requirements. FDA participates in MDSAP and has a policy that it "may" accept MDSAP audit reports in lieu of routine surveillance inspections conducted by the FDA. The FDA's final rule explained that the implementation of the QMSR will not change the voluntary nature of MDSAP or the FDA's policy regarding MDSAP audit reports.

→ *Will my firm need to hire consultants to transition into QMSR compliance?*

Most firms will benefit from hiring consultants to transition into QMSR compliance. The complexity of aligning with ISO 13485:2016 and addressing new FDA requirements may require specialized expertise that many companies don't have in-house. Consultants can provide valuable guidance in areas such as gap analysis, risk management, quality system updates, and regulatory interpretation. They can also help streamline the transition process, ensuring efficiency and thoroughness. However, the need for consultants will depend on your company's size, current QMS maturity, in-house expertise, and familiarity with ISO 13485:2016. ***Contact us*** to start the conversation about QMSR compliance.

Next Steps for QMSR Transition

We strongly suggest not waiting to begin your transition to QMSR. Qualified consultants will be in huge demand, and work projects may often be more extensive than initially thought. Do not push this out.

Here's the high-level transition strategy we're advising impacted device firms take now:

1. **Familiarize yourself with the QMSR final rule.** First and foremost, if you haven't already reviewed the final ruling, now is the crucial time to do so. Understanding the specifics of the ruling is essential for any medical device manufacturer. The FDA Group is ready to assist and guide you through this transition period, providing hands-on support and recommendations to navigate these changes effectively.
2. **Immerse yourself in ISO 13485:2016 and train your team on it.** Begin by developing a comprehensive training program for your team on the standard. This training should cover all aspects of the standard, ensuring your team is well-versed in its requirements and how they apply to your operations. If you haven't already, you can purchase ISO 13485:2016 ***here***.
3. **Conduct a comprehensive system assessment and gap analysis.** If ISO 13485:2016 has not been fully integrated into your QMS, or it's been a while since you've audited on it, now is the critical time to conduct a thorough assessment. Identify any gaps between your current QMS practices and the requirements of ISO 13485:2016. This gap analysis will serve as the foundation for your transition plan. Contact us to get gap analysis support from qualified QSR/ISO consultants.
4. **Conduct a risk management gap assessment and training program.** Perform a detailed risk management gap assessment to evaluate how well risk management is integrated into your QMS and throughout the total product lifecycle. This will highlight areas needing improvement and guide the development of strategies to address these gaps. Again, contact us to resource this project. Given the emphasis on risk management in ISO 13485:2016, ensure your team understands the importance of this component. Training should include risk management principles and its application throughout the product lifecycle.
5. **Draft a Quality Transition Plan.** Start working on a Quality Plan that outlines the steps and measures needed to transition your QMS to meet the new requirements. This plan should detail actionable steps, assigned responsibilities, deadlines, and metrics for tracking progress. We can do this for you or with you.
6. **Communicate with suppliers.** Ensure that your critical suppliers know the FDA's plans and understand the implications for your quality system. Working closely with your suppliers is vital to ensure their systems and processes will align with the new requirements. This may involve reviewing and adjusting contracts, conducting joint training sessions, or facilitating gap analyses to identify necessary adjustments. Again, we can help.

A QMSR Transition Checklist

- ❑ Have you thoroughly reviewed the QMSR final rule?
- ❑ Are you familiar with the significant changes from the QSR to QMSR, including the harmonization with ISO 13485:2016?
- ❑ Has your team been trained on the ISO 13485:2016 standard, and if not, do you have a plan to execute that training?
- ❑ Do you understand at a practical level how ISO 13485:2016 integrates with the QMSR, especially in risk management and record control areas?
- ❑ Have you conducted a comprehensive gap analysis to identify discrepancies between your current QMS and ISO 13485:2016/ QMSR requirements? Are there specific areas (e.g., risk management, device labeling, and packaging) where gaps were identified?
- ❑ Do you understand how the QMSR interacts with other FDA regulations and the FD&C Act, especially in areas where conflicts may arise (e.g., definitions of "device" and "labeling")?
- ❑ Have you evaluated how well risk management is integrated into your QMS and across the product lifecycle?
- ❑ Is there a plan to address gaps in risk management, possibly incorporating ISO 14971 for a comprehensive risk management program?
- ❑ Are you prepared to draft Quality Plan to transition your QMS to the new requirements of QMSR? Does the plan include specific steps, responsibilities, deadlines, and metrics for tracking progress?
- ❑ Do you have a plan to communicate with your critical suppliers about the FDA's plans and the implications for your quality system?
- ❑ How will you implement measures to ensure your suppliers' systems and processes align with the new QMSR requirements?
- ❑ Is there an ongoing training program to update your team on ISO 13485:2016 and the QMSR? Have you considered external training or consulting to enhance understanding and implementation of the new requirements?
- ❑ Are you prepared to update documents and records to reference the QMSR and ensure compliance with electronic records and signatures as per 21 CFR Part 11?
- ❑ Have you reviewed and adjusted your procedures for controlling and maintaining records, including complaint and service records, in alignment with the QMSR?
- ❑ Have you planned to conduct internal audits or mock inspections to assess readiness for FDA inspections under the QMSR once your QMS is prepared?
- ❑ Are you monitoring updates from the FDA regarding inspection guidelines and the QSIT)?
- ❑ Are you prepared for the legal implications of the QMSR, including the requirement that non-compliance renders a device adulterated?
- ❑ Is there a system in place to continuously monitor the effectiveness of your QMS under the QMSR and make necessary improvements?
- ❑ Have you established mechanisms for capturing and responding to feedback from internal and external stakeholders about QMSR implementation?

How The FDA Group Can Support Your QMSR Transition

The importance of developing, implementing, maintaining, and continually improving a compliant QMS cannot be emphasized enough. These critical processes are pivotal in enhancing company value and crucial in ensuring patient safety and the delivery of high-quality medical devices to those in need.

The FDA Group, with its extensive consulting network, is perfectly positioned to help you navigate the evolving QMS landscape efficiently while ensuring compliance through:

- **Gap Assessments:** We Conduct thorough gap assessments against ISO 13485:2016 and the FDA's QMSR, identifying areas of non-conformance and opportunities for improvement.
- **QMS Transition Planning:** We assist in developing a comprehensive transition plan for the QMSR, addressing and resolving any gaps identified during the gap assessment phase.
- **Inspection Preparedness:** We offer audits and mock inspections tailored to your QMS based on applicable standards and regulations to ensure readiness for actual regulatory inspections.
- **Risk Management Enhancements:** We evaluate and assess your existing risk management procedures, plans, reports, and records. The FDA Group can also assist in the development and implementation of comprehensive risk analyses, plans, and reports to strengthen this critical aspect of your QMS.
- **Supplier Quality Management:** We conduct quality audits on your suppliers to ensure their compliance with relevant standards and regulations, thereby ensuring the integrity of your supply chain.

Contact us and get the conversation started about QMSR transition.

Learn more about our services and contact us today to take the first step toward ensuring your QMSR transition completed successfully—on time and on budget.

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Who is The FDA Group?

The FDA Group helps life science organizations rapidly access the industry's best consultants, contractors, and candidates. Our resources assist in every stage of the product lifecycle, from clinical development to commercialization, with a focus in Quality Assurance, Regulatory Affairs, and Clinical Operations.

Whether you need project support or need to fill a single role or multiple roles on your team, we connect you to life science professionals with experience and expertise across functions, product lifecycle phases, and locations to augment and scale your team through consulting projects, staff augmentation, and FTE recruitment.

We help thousands of firms, including 17 of the top 25 global pharmaceutical, biotech, and medical device companies, find the resources they need, when and where they need them, through the optimal workforce model. Our resources are located in several dozen countries and have expertise throughout the life sciences. All of our services are backed by a Total Quality Guarantee.