

White Paper

# How to Effectively Transition to the FDA's New Quality Management System Regulation (QMSR)





## **The transition is happening soon. Is your company ready for all that it entails?**

The U.S. Food and Drug Administration (FDA) is undergoing a significant transformation in its regulatory framework for medical device manufacturers, transitioning from the Quality System Regulation (QSR) to the Quality Management System Regulation (QMSR). This transition seeks to align with international standards, particularly ISO 13485, and improve the consistency, safety, and effectiveness of medical devices. This white paper discusses the key drivers of this change, the impact on manufacturers, and the steps they must take to ensure compliance with the new regulatory requirements.

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### **Overview of the Transition:**

Since 1996, the U.S. Food and Drug Administration (FDA) has relied on the Quality System Regulation (QSR), codified under 21 CFR Part 820, to govern the design, manufacture, and distribution of medical devices in the United States, ensuring safety and effectiveness through detailed procedural requirements like design controls, production processes, and corrective actions. However, as global standards evolved with the International Organization for Standardization's ISO 13485—first published in 1996 and updated in 2003 and 2016, emphasizing a risk-based, process-oriented approach—the FDA recognized the need for alignment, especially by the early 2020s when maintaining a distinct QSR created duplicative compliance burdens for globally operating manufacturers. This led to a rulemaking process initiated in 2021 to align 21 CFR Part 820 with ISO 13485:2016, culminating in the finalization of the Quality Management System Regulation (QMSR) on February 2, 2024, marking a significant shift to a modernized, globally harmonized quality management system.

This white paper explores the implications of this transition, its key differences from the QSR, and its impact on the medical device industry, highlighting the FDA's strategic move to streamline regulations, reduce redundancy, and enhance competitiveness for U.S. manufacturers while maintaining stringent safety standards.

# 9 Key Changes to Consider as Part of the QSR to QMSR Transition

The QMSR replaces the QSR by incorporating ISO 13485:2016 by reference, with supplementary FDA-specific requirements. Below are the primary differences and implications:

## 1. Harmonization With ISO 13485:

The QMSR adopts ISO 13485:2016 as its foundation, shifting from the QSR's prescriptive requirements to a flexible, risk-based framework that aligns U.S. regulations with global standards (e.g., European Union, Canada, and Japan), simplifying compliance for multinational firms and facilitating easier market entry by emphasizing outcomes over specific procedures like those in 21 CFR 820.50.

By aligning with ISO 13485, the QMSR integrates risk management, design controls, and post-market surveillance, offering a more comprehensive and globally oriented approach compared to the QSR, enabling manufacturers already compliant with ISO 13485 to adapt more easily while tailoring processes to meet core quality objectives.

## 2. Risk Management Integration:

The QMSR, aligned with ISO 13485 and ISO 14971, embeds a comprehensive risk-based approach throughout the medical device lifecycle, from design to post-market surveillance, unlike the QSR, which addressed risk implicitly, primarily through design controls, requiring manufacturers to systematically identify, assess, and mitigate risks.

Manufacturers must explicitly document risk-based decision-making under the QMSR, necessitating updates to existing QMS processes to implement stringent procedures for risk analysis, control, and evaluation across product design, manufacturing, and post-market phases.

The QMSR's emphasis on proactive risk management aligns with modern medical device industry practices, surpassing the QSR's limited risk provisions by requiring a holistic integration of risk management to ensure effective risk mitigation throughout the entire product lifecycle.

## 3. Terminology and Definitions:

The QMSR adopts ISO 13485 terminology, such as "top management" instead of "management with executive responsibility," and eliminates QSR-specific terms like "device master record" in favor of broader concepts like "product realization." This shift may necessitate retraining and documentation revisions.

The FDA retains authority to interpret terms within the U.S. context, adding definitions (e.g., "manufacturer" per 21 CFR 803) to ensure clarity.

#### **4. FDA-Specific Requirements:**

While ISO 13485 is the backbone, the QMSR includes additional mandates:

- Compliance with labeling and Unique Device Identification (UDI) requirements under 21 CFR Parts 801 and 830.
- Adherence to medical device reporting (MDR) obligations under 21 CFR Part 803.
- Records maintenance for FDA inspections, including traceability to ISO 13485 clauses.

These additions ensure that U.S.-specific public health safeguards remain intact.

#### **5. Transition Timeline:**

The QMSR took effect on February 2, 2024, with a two-year transition period ending February 2, 2026. Until then, manufacturers can comply with either the QSR or QMSR, but post-2026, only the QMSR will apply.

While larger firms or those in the Medical Device Single Audit Program (MDSAP) are likely further along due to prior ISO 13485 alignment, smaller firms may lag due to resource constraints. Based on the FDA's 2018-2020 Establishment Registration database, the FDA estimates that the QMSR will apply to approximately 6,500–7,000 U.S. medical device establishments.

Currently all estimates are speculative, as no comprehensive survey data exists, but it's reasonable to estimate that a significant portion of larger or globally operating U.S. manufacturers (potentially 30%–50% of the total, based on their ISO 13485 alignment) are close to QMSR readiness, while smaller, U.S.-focused firms are less likely to have completed the transition, possibly representing a lower percentage (10%–20%). The actual percentage likely varies by company size, market scope, and device risk class.

#### **6. Improved Focus on Device Safety and Performance:**

QMSR will strengthen the focus on ensuring that medical devices perform as intended and remain safe throughout their lifecycle. This includes clear requirements for the collection and analysis of post-market surveillance data and feedback, allowing manufacturers to make adjustments to their devices in real time and reducing the likelihood of safety issues arising after market introduction.

#### **7. Technological Advancements:**

The medical device industry is increasingly driven by cutting-edge technologies, such as artificial intelligence (AI), machine learning, and the Internet of Things (IoT). QMSR takes these advancements into account by requiring manufacturers to implement quality systems that are flexible and adaptable to these rapidly evolving technologies.

#### **8. Post-Market Surveillance:**

QMSR places a stronger emphasis on post-market surveillance and feedback loops. Manufacturers will be required to collect, analyze, and act on data related to device performance and safety after the device has entered the market. This is designed to enable quicker identification of potential safety issues and provide a continuous improvement mechanism for medical devices.

## 9. Design and Development Controls:

The QMSR introduces more rigorous design and development controls, including enhanced documentation and traceability requirements. Manufacturers will need to ensure that every design change is well documented, and the rationale for such changes is clear and traceable.

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# Implications for the Medical Device Industry

Manufacturers, both large and small, will need to make significant adjustments to meet the new requirements of QMSR. These adjustments can include:

## Reduced Compliance Burden:

For companies already certified to ISO 13485, the transition minimizes the need for dual systems, cutting costs and simplifying audits. This is particularly beneficial for small and mid-sized enterprises exporting to multiple regions.

## Enhanced Global Competitiveness:

Alignment with ISO 13485 positions U.S. manufacturers to compete more effectively in international markets, where regulators often require ISO certification. This could accelerate market entry and reduce trade barriers.

## Challenges in Implementation:

- Firms solely compliant with the QSR face a steeper adjustment, requiring updates to risk management, documentation, and supplier controls. The shift from a checklist mentality to a process-oriented mindset may strain resources, especially for smaller organizations.
- The FDA's supplemental requirements (e.g., UDI and MDR) mean that full reliance on ISO 13485 certification alone is insufficient, necessitating tailored adjustments.

## Inspection and Enforcement:

The FDA has revised its inspection protocols to reflect the QMSR, focusing on ISO 13485 clauses while verifying U.S.-specific elements. This could lead to initial inconsistencies as inspectors adapt, but long-term alignment should improve efficiency. Below are six key differences in how FDA inspections will be conducted under the QMSR, based on available information:

1. **Shift From QSIT to a New Inspection Approach:** The FDA currently uses the Quality System Inspection Technique (QSIT) for inspections under the QSR. Under the QMSR, the FDA intends to replace or revise QSIT with a new inspection process aligned with ISO 13485:2016 requirements. While specific details of this new approach are not yet public, the FDA has stated it will develop and implement this process by the QMSR effective date. The new approach will likely focus on verifying compliance with ISO 13485's risk-based and process-oriented framework.

2. **Increased Focus on Risk Management:** The QMSR integrates risk management throughout the product lifecycle, as emphasized in ISO 13485 and ISO 14971. Inspections will likely place greater scrutiny on how manufacturers identify, assess, and mitigate risks across design, manufacturing, and post-market phases. Unlike the QSR, which addressed risk primarily in design validation, the QMSR requires a systematic, documented risk-based approach, and inspectors will expect evidence of this integration.
3. **Access to Previously Exempt Records:** Under the QSR, management reviews, internal quality audits, and supplier audit reports were exempt from FDA inspection to encourage candid internal discussions (21 CFR 820.180(c)). The QMSR removes this exemption, aligning with ISO 13485, which does not protect these records. FDA inspectors will now have access to these documents, potentially increasing scrutiny of management commitment, internal audit processes, and supplier oversight. Manufacturers will need to ensure these records are robust and defensible, as they may influence inspection outcomes.
4. **Enhanced Labeling and Packaging Oversight:** The QMSR retains specific QSR requirements for labeling and packaging controls (21 CFR 820.45), which go beyond ISO 13485's Clause 7.5.1. Inspections will likely emphasize detailed procedures for ensuring labeling integrity, human inspection of labeling, and packaging processes to prevent mix-ups or errors, which are common causes of recalls.
5. **No Exemption for ISO 13485 Certification:** While the QMSR incorporates ISO 13485, holding an ISO 13485 certificate does not exempt manufacturers from FDA inspections, nor does the FDA issue QMSR compliance certificates. Inspections will remain rigorous, focusing on compliance with both ISO 13485 and additional QMSR requirements, such as UDI and complaint records. Participation in MDSAP may allow some audit reports to substitute for routine FDA inspections, but the FDA will still conduct its own inspections to verify compliance.
6. **Potential for Stricter Enforcement:** FDA inspections are enforcement-based, with the agency retaining authority to issue Form 483 citations and Warning Letters or escalate to actions like seizures or injunctions for noncompliance. Unlike Notified Body audits, which may be more collaborative, FDA inspections under the QMSR will likely remain stringent, with a focus on regulatory compliance and patient safety. Manufacturers should prepare for increased accountability, especially with the removal of record exemptions.

## Updating Quality Management Systems:

Manufacturers will need to update their existing quality management systems (QMS) to align with the new regulatory framework. This may involve revising internal procedures, documentation, and software systems to ensure they meet the QMSR's requirements.

## **Training and Education:**

Employees across various functions, from design and development to quality assurance and regulatory affairs, will need to be trained on the new QMSR requirements. This includes an understanding of risk management processes, post-market surveillance practices, and how to implement quality systems in line with the FDA's updated regulations.

## **Resource Allocation:**

The implementation of a QMSR-compliant system may require additional resources, such as hiring personnel with expertise in risk management, post-market surveillance, and quality systems. Smaller manufacturers, in particular, may find this transition challenging as it may require a significant investment of time and financial resources.

## **Impact on New Product Approvals:**

Manufacturers seeking approval for new medical devices will need to demonstrate compliance with QMSR as part of the premarket approval process. This could mean additional scrutiny in the FDA's review process, as the agency will now be looking for more comprehensive evidence of quality management practices.

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# **Steps for Transition**

The FDA is training its inspectors and updating IT systems, forms, and guidance to reflect QMSR requirements, but no detailed inspection protocol has been released to date. While the FDA aims to streamline inspections through global harmonization, the transition may introduce challenges, particularly for U.S.-only manufacturers. The lack of detailed guidance on the new inspection process underscores the need for proactive preparation.

To successfully transition from QSR to QMSR, manufacturers should consider taking the following four steps:

### **1. Perform a Gap Analysis**

Conduct a thorough assessment of current quality management systems to identify gaps between QSR requirements and the new QMSR framework. This will allow manufacturers to understand where changes are needed and prioritize them accordingly.

### **2. Develop a Transition Plan**

Develop a detailed plan for updating processes, training staff, and ensuring ongoing compliance with QMSR. This plan should include timelines, resources, and milestones to ensure a smooth transition.

### 3. Implement Risk Management Processes

Revise or establish risk management processes that are aligned with ISO 14971, the international standard for risk management in medical devices. Ensure that these processes are integrated throughout the product lifecycle, from design to post-market activities.

### 4. Engage Stakeholders

Engage all stakeholders, including regulatory bodies, suppliers, and customers, to ensure that they are aware of the upcoming changes and that their processes are aligned with the new regulations.

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## Inspections: Who Will Be First

The FDA's approach to inspecting medical device manufacturers under the QMSR does not explicitly prioritize smaller manufacturers over larger ones. However, based on the FDA's historical inspection practices, regulatory framework, and the transition to QMSR, we can infer the likelihood and factors influencing inspection prioritization:

- **Risk-Based Inspection Prioritization:** The FDA has consistently prioritized inspections based on risk, as outlined in its inspection protocols for the QSIT. Under the QMSR, which aligns with ISO 13485:2016's risk-based approach, this focus will intensify. Smaller manufacturers producing high-risk devices (e.g., Class III devices like implants or life-sustaining equipment) or those with a history of noncompliance, recalls, or adverse event reports are more likely to be inspected earlier, regardless of size. Larger manufacturers with similar risk profiles or broader market impact may also be prioritized.
- **QMSR Transition Considerations:** The QMSR's alignment with ISO 13485 may ease the transition for larger manufacturers already compliant with international standards, potentially reducing their immediate inspection priority if they demonstrate strong compliance. Smaller manufacturers, particularly those only aligned with the QSR and lacking ISO 13485 experience, may face challenges adapting to the QMSR's risk-based and documentation requirements (e.g., management reviews and internal audits). The FDA may prioritize these firms to ensure they meet the new standard, especially if they produce critical devices or have a history of issues.
- **Resource and Practical Constraints:** The FDA's inspection resources are limited, with approximately 1,000–1,200 medical device inspections conducted annually (based on pre-QMSR data). The agency is training inspectors and updating systems for the QMSR, which may lead to a phased approach. Smaller manufacturers with fewer devices or simpler operations might be inspected earlier as “low-hanging fruit” to test the new inspection process, while larger, more complex firms could be scheduled later to allow for comprehensive preparation. However, this is speculative, as the FDA has not released a specific QMSR inspection schedule.



- **MDSAP and Global Alignment:** Manufacturers participating in the MDSAP may have their audit reports accepted in lieu of routine FDA inspections, potentially delaying direct FDA visits. Larger manufacturers are more likely to participate in MDSAP due to their global operations, which could shift early inspection focus to smaller, non-MDSAP firms. However, the FDA retains authority for “for cause” inspections (e.g., complaints or recalls).
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## Critical Considerations

While the FDA touts the QMSR as a progressive step, a critical lens reveals nuances worth examining. The agency’s claim of “no significant impact” on safety overlooks the practical challenges of transitioning, particularly for legacy manufacturers entrenched in QSR practices. The flexibility of ISO 13485, while advantageous, risks inconsistency if firms interpret requirements too loosely without robust FDA guidance. Moreover, the reliance on a static 2016 standard raises questions about future updates—will the QMSR adapt if ISO 13485 evolves again?

The transition also assumes industry readiness, yet as of mid-2025, anecdotal evidence suggests uneven progress. Larger firms with global operations are ahead, leveraging existing ISO certifications, while smaller players lag, grappling with resource constraints. The FDA’s limited issuance of detailed transition guidance beyond the final rule amplifies this disparity, potentially favoring well-resourced entities.

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## Conclusion

The transition from QSR to QMSR represents a significant shift in the FDA’s approach to regulating medical device quality. By aligning with ISO 13485, the FDA is not only improving regulatory consistency but also fostering a more robust and flexible approach to managing device quality, safety, and risk. While the transition may present challenges for manufacturers, it also offers the opportunity to enhance quality systems and improve overall device safety and performance. Manufacturers who start preparing early and embrace the changes are likely to gain a competitive advantage in a rapidly evolving global marketplace.

# Adapt to Evolving Medical Device Manufacturing Regulations With MasterControl

Harmonizing with the new QMSR demands more than makeshift adjustments. Medical device manufacturers need a strategic approach to quality management that can adapt to evolving regulatory frameworks. Rather than viewing harmonization as merely another compliance challenge, industry leaders are leveraging this opportunity to transform their quality operations through intelligent digital platforms.

Successfully navigating regulatory changes requires true quality transformation. MasterControl's Quality Excellence (Qx) solution provides a cloud-based platform specifically designed to help medical device manufacturers adapt to the evolving regulatory landscape while driving operational excellence through:

- **Adaptive document control:** Automatically manage documentation requirements across FDA QMSR and ISO 13485 standards, eliminating duplication of effort, reducing document lifecycle times by 30%-50%, and ensuring alignment with the latest harmonized requirements.
- **Risk-based training management:** Drive competency, not just compliance, through intelligent training that automatically adapts to regulatory changes, tracks comprehension, and ensures all personnel understand new requirements across quality system touchpoints.
- **Integrated audit readiness:** Transform audits from frenetic periodic events to continuous states of readiness through real-time compliance monitoring, automated gap analysis against harmonized standards, and predictive insights that identify potential issues before they become audit findings.
- **Holistic risk management:** Move beyond siloed risk assessments to implement the comprehensive risk-based approach demanded by both FDA and ISO frameworks, connecting risk data across the product lifecycle and quality ecosystem.
- **No-code quality event workflows:** Respond to regulatory evolution by rapidly configuring quality processes that align with harmonized requirements without IT dependency, enabling quality teams to implement changes within hours rather than months.

## Establish Manufacturing Excellence Within a Harmonized Regulatory Framework

MasterControl's Manufacturing Excellence (Mx) solution operates on the same intelligent platform as Quality Excellence, creating a single source of truth that embeds quality directly into production processes. This connected approach is uniquely suited to help organizations meet harmonized requirements while accelerating production and market access. By uniting quality and manufacturing processes within a single platform, medical device companies can benefit from:

- **Unified digital production records:** Eliminate paper-based processes that create compliance gaps between quality and manufacturing with fully digitized device history records (DHRs) that enforce harmonized requirements at every step.
- **Intelligent electronic batch records (EBRs):** Automatically adapt manufacturing documentation to evolving regulatory requirements, ensuring production processes remain compliant with both FDA and ISO standards without manufacturing disruption.
- **AI-powered error prevention:** Deploy intelligent in-line checks that enforce harmonized requirements during production, reducing deviations by up to 90% while capturing the data needed to demonstrate compliance under both regulatory frameworks.
- **Real-time document control at the production line:** Ensure manufacturing always executes against the current approved procedures that align with harmonized standards, eliminating the risk of using outdated work instructions.
- **Data-driven manufacturing intelligence:** Transform production data into actionable insights through advanced analytics that support continuous improvement while maintaining the evidence needed for regulatory submissions across markets.
- **Closed-loop quality and manufacturing processes:** Connect quality events directly to production activities, enabling immediate corrective actions and preventive measures that satisfy both FDA and ISO requirements while maintaining production continuity.

By adopting MasterControl's connected platform approach, medical device manufacturers can transform regulatory harmonization from a compliance challenge into a strategic advantage—reducing time to market, improving product quality, and creating sustainable compliance that adapts as regulatory requirements continue to evolve.

## References:

1. **"Quality System Regulation (QSR),"** FDA website, Jan. 31. 2024.
2. **"Quality Management System Regulation: Final Rule Amending the Quality System Regulation – Frequently Asked Questions,"** FDA website, Aug. 7, 2024.
3. **"ISO 13485:2016 - Medical Devices – Quality Management Systems,"** International Organization for Standardization (ISO), reviewed/confirmed in 2020.
4. **"ISO 14971:2019 - Medical Devices – Application of Risk Management to Medical Devices,"** International Organization for Standardization (ISO), reviewed/confirmed in 2025.

## About the Author

Spencer Walker, MSc, brings over two decades of experience in the medical industry, with a specialized focus on medical devices since 2006. He launched his independent consulting career in 2014 and established Peak Regulatory Consulting in 2020. His expertise centers on developing FDA and international regulatory strategies, managing submissions, and designing robust quality management systems (QMS) compliant with ISO 13485:2016 and the FDA's Quality Management System Regulation (QMSR). Spencer partners with companies to build and optimize ISO 13485-compliant QMS, ensuring alignment with global standards and facilitating market entry. Since 2016, he has also worked with the University of Utah's Center for Medical Innovation, contributing to innovative and cutting-edge medical device development and regulatory compliance.

### About MasterControl

MasterControl Solutions Inc. is a leading provider of cloud-based quality, manufacturing, and asset management software for life sciences and other regulated industries. For three decades, our mission has been the same as that of our customers – to bring life-changing products to more people sooner. MasterControl helps organizations digitize, automate, and connect quality, manufacturing, and asset management processes and has a proven track record of improving product quality, reducing costs, and accelerating time to market. Over 1,100 companies worldwide use MasterControl to streamline operations, maintain compliance, manage critical assets and equipment, easily analyze and interpret large amounts of data, and visualize business insights in real time.

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