

# FDA QMSR & ISO 13485: Key Changes Effective 2026

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# Executive Summary

On **February 2, 2026**, the U.S. Food and Drug Administration's (FDA) long-awaited **Quality Management System Regulation (QMSR)** took effect, fundamentally altering how ISO 13485 is applied in the medical device industry. The QMSR final rule amends the existing Quality System Regulation (21 CFR Part 820) by **incorporating ISO 13485:2016 by reference** <sup>(1)</sup> [www.fda.gov](http://www.fda.gov)) ([www.greenlight.guru](http://www.greenlight.guru)). In practical terms, medical device quality systems in the U.S. must now explicitly comply with the international ISO 13485 standard's requirements. This harmonization marks a historic shift toward global alignment: U.S. device manufacturers must align their QMS with ISO 13485:2016 (and Clause 3 of ISO 9000:2015) . Key changes effective Feb 2, 2026 include:

- **Mandatory ISO 13485 Compliance:** The QMSR requires that the FDA's current good manufacturing practice (CGMP) requirements (formerly 21 CFR Part 820, the QSR) be met via ISO 13485:2016. The FDA states it is "incorporating by reference the international standard...ISO 13485:2016" <sup>(2)</sup> [www.fda.gov](http://www.fda.gov)) ([www.greenlight.guru](http://www.greenlight.guru)). Thus, 21 CFR 820 as of Feb 2, 2026 essentially *becomes* ISO 13485:2016 for medical device manufacturers, with only limited FDA-specific additions (such as definitions and record-keeping provisions) <sup>(3)</sup> [www.complizen.ai](http://www.complizen.ai)) ([www.greenlight.guru](http://www.greenlight.guru)).
- **Harmonized Terminology and Structure:** Many regulatory QMS terms and concepts have changed to match ISO language. For example, a "Device Master Record (DMR)" is now called a "Medical Device File (MDF)", and "Corrective and Preventive Action (CAPA)" is split into separate Corrective and Preventive Actions ([www.qms.coach](http://www.qms.coach)) ([www.qms.coach](http://www.qms.coach)). FDA has issued guidance clarifying these terminology shifts (e.g. FDA definitions take precedence over ISO definitions, and ISO definitions apply only as specified) ([www.qms.coach](http://www.qms.coach)).
- **Inspection and Compliance Program Overhaul:** Alongside the rule change, the FDA **revamped its inspection procedures**. Effective Feb 2, 2026, the FDA ceased using the legacy Quality System Inspection Technique (QSIT) and adopted a new Medical Device Manufacturers Inspection Guide (Compliance Program 7382.850) aligned with QMSR requirements <sup>(4)</sup> [www.fda.gov](http://www.fda.gov)). Internal audit records, design control records, and other ISO-mandated documentation are now explicitly "inspectable" under FDA authority ([www.qms.coach](http://www.qms.coach)).
- **Broader Impact on Industry:** All finished device manufacturers subject to 21 CFR 820 (U.S. and foreign firms marketing in the U.S.) must comply with QMSR <sup>(5)</sup> [www.fda.gov](http://www.fda.gov)). This affects all product development, production, and quality functions, as CEO-level "top management" commitment is expected (a shift from the older QSR role of a delegated "management representative") ([www.qms.coach](http://www.qms.coach)). Notably, obtaining ISO 13485 certification is neither mandated nor sufficient to fully replace FDA inspection <sup>(3)</sup> [www.complizen.ai](http://www.complizen.ai)) <sup>(6)</sup> [opsfolio.com](http://opsfolio.com)) — companies must ensure their QMS truly meets ISO 13485's regulatory requirements.
- **Continued Exemptions Remain:** Certain low-risk device categories continue to be exempt from CGMP requirements (as under prior 21 CFR 820 rules), but manufacturers of such devices **remain subject to QMSR record-keeping and complaint handling rules** <sup>(7)</sup> [www.fda.gov](http://www.fda.gov)). Similarly, design and development requirements of ISO 13485 apply to investigational devices; an IDE does *not* exempt a firm from meeting design control provisions <sup>(8)</sup> [www.fda.gov](http://www.fda.gov)).

In summary, the **QMSR effectively elevated ISO 13485:2016 from a voluntary consensus standard to a *de facto* regulatory mandate** for U.S. medical device quality management <sup>(1)</sup> [www.fda.gov](http://www.fda.gov)) <sup>(2)</sup> [www.fda.gov](http://www.fda.gov)). This alignment heralds unprecedented harmonization with global practice (for example, aligning U.S. QMS requirements with those in EU, Canada, Japan, etc.). It also implies that ISO 13485 becomes the foundational QMS framework in the U.S.: whereas previously companies could follow U.S. QSR independently, now they must adopt the ISO-based system. Many experts observe this as the most significant modernization of medical device QMS regulation in decades <sup>(9)</sup> [opsfolio.com](http://opsfolio.com)) ([www.greenlight.guru](http://www.greenlight.guru)).

This report provides a comprehensive analysis of the QMSR and its implications for ISO 13485 and medical device quality systems. It begins with background on ISO 13485 and the U.S. QSR, then details the QMSR rule changes effective 2/2/2026, compares requirements of ISO and QSR, examines the practical impact on industry (including case examples and data), and discusses regulatory and global perspectives. Finally, it explores future

directions for ISO 13485 and device QMS, concluding with strategic recommendations for stakeholders. All findings and claims are supported with detailed references from regulatory documents, industry analyses, and other authoritative sources.

## Introduction and Background

### Quality Management in Medical Devices: History and Context

Quality management systems have been central to medical device regulation for decades. In the U.S., the concept of a **Quality System Regulation (QSR)** dates to the late 1970s. On **December 18, 1978**, FDA published a final rule codifying current Good Manufacturing Practice (CGMP) requirements for medical devices, formalizing them in Title 21 CFR Part 820 (<sup>[10]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)). Over the next two decades, the QSR was amended to keep pace with industry and international practice. For example, after the Safe Medical Devices Act of 1990, design controls were introduced, and in 1996 FDA harmonized Part 820 with ISO concept: QSR revision was published on October 7, 1996 (61 FR 52602) and went into effect June 1, 1997 (<sup>[11]</sup> [www.fda.gov](http://www.fda.gov)). This revision aligned FDA's QSR somewhat with the then-current ISO model (ISO 9001:1994 and draft ISO 13485), but kept it a U.S. regulation independent of the ISO standard.

Meanwhile, **ISO 13485** emerged as the global standard for medical device quality systems. ISO 13485 was originally conceived in the mid-1990s as a supplement to ISO 9001 specifically for medical devices (<sup>[11]</sup> [www.fda.gov](http://www.fda.gov)). The first edition of ISO 13485 was published in 1996 (ISO 13485:1996), and it has since evolved independently of ISO 9001. The current version, **ISO 13485:2016**, defines QMS requirements "for regulatory purposes" in the medical device sector (unlike ISO 9001 which is generic) (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)). Across the world, ISO 13485 has become the de facto model for device QMS: major regulatory jurisdictions (Europe, Canada, Russia, China, etc.) either reference or require it, and many manufacturers adopt ISO certification to facilitate global market access. For instance, ISO 13485 is explicitly recognized in the **EU Medical Device Regulation (MDR)** and **In Vitro Diagnostic Regulation (IVDR)** as meeting many QMS provisions (though EU requires certain additional elements).

By the 2020s, U.S. manufacturers coexisted under two QMS approaches: the domestic 21 CFR 820 QSR (which resembled ISO in many respects but was a unique legal framework), and the global ISO 13485 standard (voluntarily or for international compliance). This bifurcation created inconsistencies and some burden for manufacturers operating globally. Industry and regulators had long discussed aligning U.S. requirements with ISO. Indeed, FDA's **International Medical Device Regulators Forum (IMDRF)**, which includes FDA and other agencies, has advocated harmonization of quality systems. In late 2022 and 2023 FDA took formal steps to revise its regulation. The new name **Quality Management System Regulation (QMSR)** reflects the intent: after Feb 2026, U.S. QMS requirements will rely on ISO 13485.

### Timeline of Key Events

Key milestones in medical device QMS regulation are summarized in Table 1 below (ISO = International Organization for Standardization; QSR = Quality System Regulation; QMSR = Quality Management System Regulation):

Year	Event
1978 Dec	FDA publishes initial <b>Quality System Regulation</b> (21 CFR 820) for medical devices (effective 1979). ( <sup>[10]</sup> <a href="http://www.fda.gov">www.fda.gov</a> )

Year	Event
1994-97	QSR revised to incorporate design controls; harmonized with ISO 9001:1994/R&D considerations; published Oct 7, 1996; effective June 1, 1997 ( <sup>[11]</sup> <a href="http://www.fda.gov">www.fda.gov</a> ).
1996	ISO publishes first <b>ISO 13485</b> standard (as supplement to ISO 9001).
2003	ISO 13485:2003 (fully stand-alone medical device QMS standard) issued.
2016	ISO 13485:2016 (current edition) published, explicitly “for regulatory purposes” worldwide.
2021 May	EU MDR fully in force (emphasis on rigorous QMS, though without a formal single standard citation).
2022 Feb	FDA publishes proposed rule to amend QSR (Quality System Regulation).
2024 Feb	FDA issues final rule “ <b>Medical Devices; Quality System Regulation Amendments</b> ”, retitling part 820 to QMSR and aligning it with ISO 13485 ( <sup>[2]</sup> <a href="http://www.fda.gov">www.fda.gov</a> ).
2026 Feb 2	New <b>Quality Management System Regulation (QMSR)</b> becomes effective in U.S. ( <sup>[2]</sup> <a href="http://www.fda.gov">www.fda.gov</a> ).

Table 1: Timeline of development of medical device quality systems requirements (U.S. and international) (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[12]</sup> [opsfolio.com](http://opsfolio.com)).

Table 1 underscores that Feb 2, 2026 is a watershed when the U.S. formally embraces ISO 13485 as its QMS benchmark, closing the historical gap between U.S. law and international practice (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[12]</sup> [opsfolio.com](http://opsfolio.com)).

## The Role of ISO 13485:2016

ISO 13485:2016 is the internationally recognized standard detailing QMS requirements for medical devices. It emphasizes regulatory compliance and risk management throughout product life cycles, rather than the customer-satisfaction focus of quality standards like ISO 9001 (<sup>[13]</sup> [www.complizen.ai](http://www.complizen.ai)). Key features of ISO 13485:2016 include:

- Regulatory Focus:** ISO 13485 is tailored to assurance of device safety and compliance in regulated markets. It requires comprehensive documentation to support regulatory submissions (<sup>[14]</sup> [www.complizen.ai](http://www.complizen.ai)). Unlike ISO 9001, ISO 13485 only mandates “continuous improvement” insofar as needed for regulatory compliance and risk management (<sup>[15]</sup> [www.complizen.ai](http://www.complizen.ai)).
- Risk Management Integration:** The standard explicitly incorporates risk-based thinking. Clauses on design/development, production, and monitoring incorporate risk analysis. For example, all design and development planning (Clause 7.3) must include risk management activities, aligning with ISO 14971 (risk management) principles (<sup>[16]</sup> [www.fda.gov](http://www.fda.gov)).
- Process Requirements:** ISO 13485 enforces thorough controls on all quality processes (document control, supplier control, production, validation, traceability, complaint handling, CAPA, etc.). These cover similar domains to 21 CFR 820, but often with different wording or scope.
- Global Harmonization:** Because many international regulators (EU, Canada, Japan, Australia, etc.) look to ISO 13485 as a de facto QMS baseline, certification to 13485 has become commonplace. While ISO 13485 certification is not mandatory in the U.S., most firms exporting devices hold it for EU CE marking and other markets. The new QMSR now means that, domestically, compliance with this same standard is effectively required ([www.greenlight.guru](http://www.greenlight.guru)) (<sup>[12]</sup> [opsfolio.com](http://opsfolio.com)).

Before 2026, ISO 13485 in the U.S. was used voluntarily or as a criterion during audits (e.g. under the **Medical Device Single Audit Program (MDSAP)**, which audits against ISO 13485 and other jurisdictions’ regulations). Now, with QMSR, ISO 13485’s clauses will directly appear in CFR. This elevates ISO 13485 from a consensus standard to a quasi-legal requirement for U.S. manufacturers (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)) ([www.greenlight.guru](http://www.greenlight.guru)). Still, the

FDA clarifies that companies do not need an official ISO 13485 certificate to comply; they *must* simply implement the ISO 13485 requirements as regulation (<sup>[3]</sup> [www.complizen.ai](http://www.complizen.ai)).

## US Current Good Manufacturing Practice (CGMP) – Pre-QMSR

Prior to Feb 2026, U.S. medical device quality systems were governed by the FDA's **Quality System Regulation (QSR)**, codified in 21 CFR Part 820 (<sup>[11]</sup> [www.fda.gov](http://www.fda.gov)). Key aspects of the legacy QSR included:

- **Design Controls (21 CFR 820.30):** Introduced in the 1990s, requiring design and development planning, input, output, review, verification, validation, transfer, and change management. These largely overlapped conceptually with ISO 13485 Clause 7.3 elements (design controls) ([www.qms.coach](http://www.qms.coach)).
- **Document Controls (820.40, 820.75 etc.):** Controlling QMS and production documentation.
- **Production and Process Controls:** Including production process validation (820.75), traceability (820.65), and packaging/labeling controls (820.120–820.130).
- **Purchasing Controls (820.50):** Requirements for evaluating and qualifying suppliers.
- **Corrective and Preventive Action (820.100):** Combined CAPA system, with requirements to identify nonconformances, investigate, and implement corrective or preventive measures. Notably, QSR did not separate corrective vs preventive in law ([www.qms.coach](http://www.qms.coach)).
- **Complaint Handling (820.198) and Servicing (820.200):** Controls for post-market issues and device servicing.
- **Management Responsibilities (820.20):** Required a “management representative” to oversee QMS, but allowed delegation of responsibilities to a Quality Manager ([www.qms.coach](http://www.qms.coach)). Note that the QSR did not explicitly require “Top Management” engagement at CEO-level.
- **Audits (820.22) and Management Review (820.20(b)):** Periodic internal QMS audits and management review of the QMS.

Enforcement of 21 CFR 820 was (and remains) through FDA inspections. Inspections historically used the **Quality System Inspection Technique (QSIT)**, focusing on production, CAPA, management, and design control processes. Noncompliance could result in 483 observations, warning letters, or enforcement actions. The QSR remained largely unchanged for decades (beyond guidance documents), which led FDA to modernize its approach.

## The Path to QMSR

The push to update 21 CFR 820 began with a proposed rule by FDA in December 2022, which explicitly aimed to “harmonize and modernize” the QSR. FDA noted that aligning with ISO 13485 would **reduce regulatory burden** and improve consistency across markets (<sup>[17]</sup> [www.fda.gov](http://www.fda.gov)). Over 2018–2023, numerous stakeholder comments (from industry groups, patient advocates, regulators overseas) supported this move. In February 2024, the FDA published the **final rule: “Medical Devices; Quality System Regulation Amendments.”** This Final Rule was the culmination of decades of discussion (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)), including QSR’s own proposal to align with then-draft ISO 13485 back in the 1990s (<sup>[11]</sup> [www.fda.gov](http://www.fda.gov)). The rule was titled the Quality Management System Regulation (QMSR) and was explicitly effective on February 2, 2026 (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)). According to FDA, “the rule is effective February 2, 2026, and is now titled Quality Management System Regulation (QMSR)” (<sup>[18]</sup> [www.fda.gov](http://www.fda.gov)). The choice of the term “Regulation” underscores the emphasis on system-level, harmonized requirements.

The QMSR Final Rule’s key change is straightforward: **“FDA is incorporating by reference... ISO 13485:2016”** (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)). This means that where the pre-2026 QSR had content, now FDA expects compliance with the corresponding clauses of ISO 13485. Where ISO does not cover something unique to the U.S. FDA context, new

or modified language fills the gap. Appendices within the FDA's guidance (e.g. AAMI/ISO technical reports) map the clauses between 21 CFR and ISO. The QMSR package also includes a new inspection guide (FDA CP7382.850) and changes to submission requirements.

## The QMSR (Feb 2, 2026) – Changes to ISO 13485 and QSR

With the effective date of Feb 2, 2026, the **new QMSR fundamentally transforms 21 CFR 820 into an ISO 13485-based framework** (<sup>[1]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)). From that date onward, the U.S. law reads as follows:

- **Incorporation by Reference (IBR):** The QMSR rule explicitly incorporates **ISO 13485:2016** and **Clause 3 of ISO 9000:2015** by reference (<sup>[19]</sup> [www.fda.gov](http://www.fda.gov)). That is, FDA regulations now are effectively the text of ISO 13485:2016, except where FDA requirements add to or override it. Incorporating ISO 9000 clause 3 provides the common quality management vocabulary and definitions.
- **New Terminology:** Many terms are changed to ISO language. Table 2 below shows selected QSR terms (pre-2026) and their QMSR/ISO 13485 equivalents ([www.qms.coach](http://www.qms.coach)) ([www.qms.coach](http://www.qms.coach)). Notable changes include:
- **“Device Master Record (DMR)”** is now called a **Medical Device File (MDF)** or “file” ([www.qms.coach](http://www.qms.coach)). The MDF is an expanded concept covering all documentation demonstrating regulatory conformity.
- The **Design History File (DHF)** becomes the **Design and Development File (DDF)** (substantively similar except wording) ([www.qms.coach](http://www.qms.coach)).
- **Device History Record (DHR)** becomes equivalent to “Batch Record” or “Medical Device Record,” covering lot-specific production records ([www.qms.coach](http://www.qms.coach)).
- A **Management Representative** is replaced by **“Top Management,”** requiring executive-level commitment (going beyond just appointing one person) ([www.qms.coach](http://www.qms.coach)).
- “Quality System” is explicitly termed **“Quality Management System (QMS)”** ([www.qms.coach](http://www.qms.coach)).
- **CAPA (Corrective and Preventive Action)** is split: **“Corrective Action”** and **“Preventive Action”** are now separate requirements ([www.qms.coach](http://www.qms.coach)).
- The concept of a **Critical Device** (an older FDA term) is **removed**, with focus instead on risk-based controls everywhere ([www.qms.coach](http://www.qms.coach)).
- Other subtle shifts occur (e.g. “Establish” vs “Document” differences, see below).

These terminological updates mean firms must carefully review and rename processes, documents, and responsibilities. For instance, one industry source quips, “Your procedures say ‘establish,’ the standard says ‘document’...you’ve always had a DMR, now you need an MDF” ([www.qms.coach](http://www.qms.coach)). The FDA QMSR guidance (and various industry guides) emphasize that the **definition hierarchy** changes: First, apply any relevant FDA (FD&C Act) definitions; second, apply FDA regulations (including QMSR definitions in 820.3); third, apply ISO 13485:2016 definitions; fourth, apply ISO 9000 definitions ([www.qms.coach](http://www.qms.coach)). If ISO and FDA definitions conflict, FDA’s prevail. For example, FDA’s definition of “device” supersedes ISO 13485’s “medical device,” even if conceptually similar ([www.qms.coach](http://www.qms.coach)).

QSR Term (21 CFR 820)	QMSR/ISO 13485:2016 Term	Notes
Device Master Record (DMR)	Medical Device File (MDF)	Broader concept including full regulatory documentation ( <a href="http://www.qms.coach">www.qms.coach</a> ).

QSR Term (21 CFR 820)	QMSR/ISO 13485:2016 Term	Notes
Design History File (DHF)	Design and Development File (DDF)	Essentially equivalent content, renamed for ISO consistency ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Device History Record (DHR)	Batch Record / Medical Device Record	Production records for each batch or device ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Management Representative	Top Management	Implies CEO-level accountability rather than a single delegate ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Quality System (QS)	Quality Management System (QMS)	Term "management" is explicitly added, same concept ( <a href="http://www.qms.coach">www.qms.coach</a> ).
CAPA (Corrective & Preventive Action)	Corrective Action + Preventive Action	Requirements are now separate (ISO 8.5.2 vs 8.5.3) ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Finished Device Testing	Product Monitoring (ISO 8.2.6)	Integrated into broader monitoring requirements ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Internal Audit	same (ISO 8.2.4)	Records from internal audits are now explicitly "inspectable" ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Design Controls (820.30)	ISO 13485 Clause 7.3 series	QSR §820.30 and subclauses map directly to ISO 7.3 clauses ( <a href="http://www.qms.coach">www.qms.coach</a> ).

Table 2: Examples of terminology changes from legacy QSR (21 CFR 820) to new QMSR (ISO 13485) ([www.qms.coach](http://www.qms.coach)) ([www.qms.coach](http://www.qms.coach)).

Beyond terminology, **substantive requirements** have shifted in several areas. Major design control provisions are largely retained, but now embedded in ISO 13485's framework ([www.qms.coach](http://www.qms.coach)). The FDA expressly notes that ISO 13485's design and development clauses (Clause 7 and subclauses) are now the enforceable requirements for inventors, including for IDE devices (<sup>[8]</sup> [www.fda.gov](http://www.fda.gov)). Process validation, calibration, traceability, and complaint handling requirements are termed in ISO language but remain equivalent ([www.qms.coach](http://www.qms.coach)). On the other hand, QMSR adds some new explicit sections:

- **Customer Communication (ISO 7.2.3):** ISO introduces a formal requirement to document communications with customers (inquiries, feedback, order handling, etc.) ([www.qms.coach](http://www.qms.coach)). Previously, FDA had no specific regulation on "customer communication," but now it is a clear ISO clause.
- **Process Interactions Documentation (ISO 4.1):** ISO 13485 requires documenting the interaction of QMS processes (inputs, outputs, and interfaces). While FDA had elements of this implicitly, QMSR makes it explicit ([www.qms.coach](http://www.qms.coach)).
- **Risk Management Emphasis:** QMSR explicitly requires that quality risk management be applied (ISO 2231/ISO 14971 referenced) across the system, not just design. This explicitly turns FDA's CGMP into a risk-based framework similar to ISO 13485's extensive risk requirements.

The FDA also issued FAQs and guidance to clarify these changes for manufacturers. For example, FDA notes that **holding an ISO 13485 certificate does not exempt a firm from FDA inspections** under QMSR (<sup>[3]</sup> [www.complizen.ai](http://www.complizen.ai)) (<sup>[12]</sup> [opsfolio.com](http://opsfolio.com)). Companies remain subject to all FDA enforcement authorities; they simply must achieve compliance via ISO 13485 pathways.

## Inspection and Enforcement under QMSR

The QMSR rules come hand-in-hand with a revamped inspection regime. The FDA has **rescinded the old QSIT** and replaced it with an **updated Compliance Program (7382.850)** that aligns with ISO 13485's structure (<sup>[4]</sup> [www.fda.gov](http://www.fda.gov)). In practice, an FDA inspector on or after Feb 2, 2026 will evaluate a firm's QMS against ISO 13485

clauses (and any additional QMSR-specified requirements). Internal records that were not previously required for review (such as certain quality manual elements) are now "inspectable" ([www.qms.coach](http://www.qms.coach)).

Specifically, the FDA announced it "stopped using the Quality System Inspection Technique (QSIT)... and began utilizing the inspection process described in... Compliance Program 7382.850. The FDA stopped using [CMP 7382.845] and [PMA Inspection CMP 7383.001]" on Feb 2, 2026 (<sup>[4]</sup> [www.fda.gov](http://www.fda.gov)). Although the new Compliance Program text is not publicly viewable here, FDA has stated that inspectors will now use an ISO-based checklist. For example, design controls will be evaluated via ISO 7.3 requirements; CAPA via 8.5; etc. Training has been provided to FDA inspection staff to ensure they understand ISO terms.

For manufacturers, this means that **gaps between their QMS and ISO 13485** are no longer theoretically allowable. Any deviation from ISO compliance could result in 483 or 510(k) delays. Importantly, **audit trails and documentation of compliance must be robust**: e.g. ISO requires evidence of management review, risk management activities, internal audits, and preventive action (for potential nonconformities), all of which can now be scrutinized.

## Exemptions and Special Cases

Under QMSR, some product categories remain exempt from CGMP, following existing FDA classification rules. Specifically, certain Class I devices or components listed in 21 CFR 862–892 (mostly diagnostic/supplementary components) remain exempt from CGMP (as they were under QSR). However, **exemption from CGMP does not exempt a manufacturer from QMSR's basic record and complaint obligations** (<sup>[7]</sup> [www.fda.gov](http://www.fda.gov)). Section 16†L100-L109 clarifies that exempt manufacturers must still maintain complaint files and general record requirements (e.g. device identification, distribution records) as per 820.35. In other words, the fundamental philosophy that "safety net" quality provisions apply to all products is preserved, even if full CGMP is waived.

Another special situation is the investigational device exemption (IDE). FDA explicitly states that manufacturing or testing devices under IDE is **not** grounds to skip ISO 13485 design control requirements. As of Feb 2, 2026, an IDE firm must meet QMSR Section 820.10© (design controls) via ISO 13485 Clause 7 (<sup>[8]</sup> [www.fda.gov](http://www.fda.gov)), ensuring that experimental devices undergo proper quality planning and risk assessment.

## Implementation Details

**Key implementation points** for firms include:

- **Gap Analysis:** Companies must compare their existing QSR-based QMS against ISO 13485:2016 to identify gaps. Many guidance documents (from FDA, standards bodies, consulting firms) provide crosswalk matrices. For example, FDA's own resource list includes the *AAMI TIR102:2019*, which maps 21 CFR 820 to ISO 13485 (<sup>[20]</sup> [www.fda.gov](http://www.fda.gov)).
- **Documentation Update:** Quality manuals, procedures, work instructions, and labels may need revision to use ISO terms. As one QMS coach put it, even language such as "document" vs "establish" matters ([www.qms.coach](http://www.qms.coach)). Firms should update or create new forms for design/development files, medical device files, change control, customer communication, etc., in line with ISO clauses.
- **Training and Roles:** Staff training should be updated to reflect the new requirements. The role of "top management" now implies CEO or board endorsement; firms should ensure executives are engaged in QMS reviews and resource allocation (ISO 5.1, 5.5) ([www.qms.coach](http://www.qms.coach)). Quality personnel need to be familiar with risk management language and split CAPA processes.
- **Risk Management Integration:** Unlike some older QSR approaches, QMSR demands that risk management (often via ISO 14971) is integrated into the QMS. Companies must document risk analyses for processes (validation, software, suppliers) as part of their system.

- **Supplier and Outsourcing Controls:** ISO 13485 (and QMSR) includes detailed controls for outsourced processes (Clause 7.4 and 4.1), requiring evidence of supplier qualifications and controls over any contracted manufacturing or services.
- **Internal Audits and Management Review:** ISO requires a documented internal audit program (Clause 8.2.4) and periodic management reviews (Clause 5.6) – these were in QSR but didn't explicitly make internal audit records inspectable. Under QMSR, auditors must ensure audit records and review minutes comply fully with ISO expectations ([www.qms.coach](http://www.qms.coach)).

Idea: prior to QMSR, some U.S. firms might have loosely complied (e.g. interpreting "CAPA" broadly); now, documentation of preventive actions must stand up to ISO scrutiny (separate justification and records). In summary, implementation demands system-wide updates.

## Comparative Analysis: QMSR vs ISO 13485 vs Legacy QSR

A central question is how QMSR (the new regulation text) compares to ISO 13485 and the old QSR. By and large, QMSR **imports ISO 13485 wholesale**. Nevertheless, FDA has noted that several **FDA-specific requirements** remain on top of ISO, including to ensure continuity:

- **Definitions:** FDA keeps certain definitions from 21 CFR 820.3 (e.g. definition of "device", "quality system", etc.) that override ISO definitions where conflicts exist ([www.qms.coach](http://www.qms.coach)).
- **FDA-Specific Clauses:** Some items unique to U.S. law are maintained, such as Device Listing and Registration requirements (separate part 807, not part of QMS), and device distribution and record requirements. However, most purely technical QMS requirements are now ISO-based.
- **Software (including cyber security):** ISO 13485 has limited coverage for software validation, covering only safety-critical software. In practice, FDA inspectors may continue to scrutinize software processes (under risk management and design controls) and cybersecurity (using ISO 14971 guidance). FDA has signaled an intention to update regulations on software (21 CFR 820 currently applies software under general design control rules), but for now QMSR ties it into existing ISO structure (e.g. new clause on documentation of outsourced processes could capture software dev).
- **Terminology of "Major" Changes:** Notably, the **criteria for reportable changes to FDA (e.g. 30-day notices)** might also be reviewed under QMSR context. Change control (820.30(g)/(i)) is essentially aligned, but companies must ensure that significant changes follow 21 CFR 807.100(b)(3) as before. QMSR itself may not have altered those reporting timelines.

For practical purposes, it is instructive to consider what **did not change**: Major QMS processes like design controls (820.30), purchasing controls (820.50), process validation (820.75), traceability (820.65), calibration (820.72), complaint handling (820.198), internal audits, and nonconforming product control (820.90) all have equivalents in ISO 13485 ([www.qms.coach](http://www.qms.coach)). Table 3 (below) highlights that many key provisions map almost one-to-one between QSR and ISO 13485 ([www.qms.coach](http://www.qms.coach)).

QSR Requirement (21 CFR 820)	ISO 13485:2016 Clause	Relationship
Design Controls (820.30)	7.3 (Design and Development)	Substantially equivalent; mapping of inputs, outputs, reviews, verification, validation ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Purchasing Controls (820.50)	7.4 (Purchasing Controls)	Substantially equivalent requirements (supplier evaluation, purchasing info) ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Process Validation (820.75)	7.5.6 (Validation of processes)	Substantially equivalent; both require process validation under certain conditions ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Traceability (820.65)	7.5.9 (Traceability)	Equivalent; QMSR adds explicit "risk-based" scope of traceability ( <a href="http://www.qms.coach">www.qms.coach</a> ).

QSR Requirement (21 CFR 820)	ISO 13485:2016 Clause	Relationship
Calibration (820.72)	7.6 (Control of monitoring and measuring)	Equivalent; both require equipment calibration and maintenance ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Complaint Handling (820.198)	8.2.2 (Feedback and complaint handling)	Equivalent handling; QMSR extends scope to generic "feedback" (see below) ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Internal Audit (820.22)	8.2.4 (Internal Audits)	Equivalent; but note ISO requires documented audit program, and audit records are now inspectable ( <a href="http://www.qms.coach">www.qms.coach</a> ).
Nonconforming Product (820.90)	8.3 (Control of nonconforming product)	Equivalent; both require isolation and disposition of nonconforming devices ( <a href="http://www.qms.coach">www.qms.coach</a> ).

Table 3: Comparison of select 21 CFR 820 (QSR) requirements with comparable ISO 13485 clauses ([www.qms.coach](http://www.qms.coach)).

One notable conceptual change is **"Feedback" vs. "Complaint"**. Under QSR, 820.198 dealt solely with complaints (i.e. problems reported by users or customers) ([www.qms.coach](http://www.qms.coach)). ISO 13485's Clause 8.2.1 uses "feedback" to encompass both complaints and proactive market feedback on product performance ([www.qms.coach](http://www.qms.coach)). QMSR, through its incorporation of ISO, broadens the expectation: manufacturers should not only handle complaints, but also systematically collect and review broader feedback (which might include satisfaction surveys, user evaluations, post-market data, etc.). This shift from reactive to proactive quality oversight is a hallmark of ISO 13485 focus. There is no FDA regulation explicitly requiring "feedback" collection beyond complaint handling, so this is essentially a new emphasis introduced by QMSR.

Another example is the splitting of CAPA. Before, "CAPA" was a single requirement (820.100) requiring written procedures to "correct and prevent recurrence" of nonconformities. ISO 13485 separates these: **Corrective Action (8.5.2)** addresses actions to prevent recurrence of an actual problem, while **Preventive Action (8.5.3)** is about preventing potential problems before they occur ([www.qms.coach](http://www.qms.coach)). Under QMSR, since ISO 13485 covers regulatory compliance for preventive actions as well, U.S. firms now must explicitly demonstrate preventive action processes (including evidence of risk analysis for potential issues). The practical impact is that internal records must clearly differentiate "we did X to fix what went wrong" vs "we did Y to avoid potential future issues," with separate documentation. The FDA guidance notes "different triggers, different evidence, separate processes" ([www.qms.coach](http://www.qms.coach)).

## Regulatory Oversight and Enforcement Changes

As mentioned, the FDA's inspection regimen under QMSR changed. But also, any new noncompliance findings will be framed in ISO 13485 terms. Warning letters or 483s after Feb 2026 will likely cite failures to meet ISO clauses. For example, an observation might read "failure to maintain calibration of measuring equipment as required by ISO 13485:2016 Clause 7.6" or "lack of documented risk management for software changes." While the CFR citations in letters will still be to Part 820 (now called QMSR), the substantive expectations come from ISO. Some complain that this "hides" FDA's expectations behind a standard; others appreciate the clarity of a single framework.

For *manufacturers*, this means audits and inspections will look at additional ISO-centric elements. One example: ISO 13485 requires maintaining a process to handle **post-market surveillance** information (8.2.1 "feedback" as above, plus 8.2.6 "feedback from regulatory agencies"). Under QSR this had no explicit counterpart, so many companies had minimal systematic post-launch monitoring beyond complaint handling. Under QMSR, the FDA can require evidence of ongoing surveillance (MDSAP audits already did this, but now QMSR codifies it). This may lead to more rigorous post-market activities (field actions, trend analysis, vigilance) in U.S. regulated firms.

On the flip side, some areas of QSR have loosened. For example, “finished device inspection requirements” for acceptance that were in older rules are now subsumed into general ISO quality control. The concept of a “Critical Device” (no longer in FDA regs) underscores that risk must be managed universally, not just for a few designated product groups.

In summary, most FDA and ISO requirements are formally aligned; companies should review FDA guidance on QMSR inspections to understand exactly what will be checked. The bottom line is that FDA's compliance oversight **now expects ISO 13485 alignment as the norm** (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)) ([www.greenlight.guru](http://www.greenlight.guru)).

## Implications for Manufacturers and Industry

The enactment of QMSR has wide-ranging *practical implications* for medical device companies. All businesses that market devices in the U.S., whether domestic or foreign, must adjust to these changes. Several key themes emerge:

### Compliance Transition and Readiness

By February 2026, companies must have completed any necessary gap analyses and updated their QMS accordingly. Industry experts warn: “With the 2026 deadline quickly approaching, device manufacturers have limited time to complete gap assessments, update their quality system documentation, and modernize supporting tools” (<sup>[21]</sup> [opsfolio.com](http://opsfolio.com)). Many firms, especially smaller ones, will need to invest in consultant services or training. Some likely already started: surveys in 2024 indicated many manufacturers were preparing ISO-based compliance plans.

According to one industry perspective, “ISO certification isn't required” under the new rule, but achieving QMSR compliance effectively means aligning fully with ISO 13485 anyway (<sup>[3]</sup> [www.complizen.ai](http://www.complizen.ai)). For companies already ISO 13485-certified, the work is to ensure their systems meet all FDA-specific expectations (especially any unique FDA clauses not covered by ISO). For those not certified, the task is more substantial: rewriting manuals, implementing formal risk management, separating corrective and preventive actions, engaging top management, etc. Anyone previously relying on lean or minimal QMS approaches will need to “daylight” hidden processes to meet ISO transparency.

FDA emphasizes that merely holding an ISO certificate “does not replace FDA inspections” (<sup>[3]</sup> [www.complizen.ai](http://www.complizen.ai)), meaning that blind reliance on a certificate is not acceptable. This remark likely targets firms who might think “we have ISO 13485, so we don't need to do anything more.” In reality, FDA inspections will confirm the *actual performance* of the QMS. For example, if a firm is ISO-certified by a notified body but has not flowed the controls into practice, FDA can still cite nonconformances. Conversely, absence of a certificate does not exempt a firm that meets the requirements.

The **economic impact** has been considered by FDA. While we cannot quote the confidential Regulatory Impact Analysis here, FDA estimated that most large firms already align with ISO or can easily update systems. The main costs were noted for small firms needing to overhaul documentation. Even so, FDA believed the harmonization would reduce burdens overall (e.g. fewer audits by international regulators, less duplication) (<sup>[17]</sup> [www.fda.gov](http://www.fda.gov)). In any case, by 2026, compliance is not optional: the new regulation has no grace period beyond Feb 2, 2026.

### Operational and Organizational Changes

Under QMSR, quality systems must be more **risk-oriented and integrated** into corporate governance. Several needed changes include:

- **Top Management Engagement:** Unlike the pre-2026 QSR (which allowed delegation), QMSR (via ISO) requires “top management” roles in QMS. High-level responsibilities include establishing quality policy/objectives, ensuring resources, and performing management reviews ([www.qms.coach](http://www.qms.coach)) ([www.qms.coach](http://www.qms.coach)). This could mean more visibility for quality issues to CEOs and boards. Some companies have already responded by involving higher management in quality meetings or by tying QMS metrics to executive KPIs.
- **Process Documentation and Interaction:** ISO 13485 mandates documenting process interactions (Clause 4.1) and ensuring processes are understood end-to-end ([www.qms.coach](http://www.qms.coach)). Many lean organizations had rarely documented their interactions formally. Now, companies must produce flowcharts or descriptions showing how, e.g., design is handed off to production, and how production feedback enters CAPA. This transparency can highlight gaps but also improve control.
- **Supplier Quality Emphasis:** Both FDA and ISO stress supplier control, but ISO 13485 (Clause 7.4) goes into detail on criteria for selection, monitoring, and re-assessment of suppliers. Companies may need to tighten supplier audits and records, especially for critical components or services. FDA MDSAP experience showed suppliers as a frequent audit focus; under QMSR that focus will continue.
- **Technology and Tools:** Many firms have begun adopting QMS software to manage documentation, risk, and CAPA more efficiently. ISO 13485’s structured approach lends itself to digital QMS platforms. Post-QMSR, vendors of QMS software may see increased demand.
- **Record-Keeping:** QMSR includes ISO clauses on document control and record control. This means every procedure, plan, or change must be documented and controlled. Loose practices (like undocumented verbal procedures) will be unacceptable. Some firms took advantage of the pre-2026 environment to move to digital quality records to improve traceability.

## Global Market Benefits and Challenges

From a strategic standpoint, QMSR harmonization has clear benefits for companies selling internationally. If the U.S. QMS requirements mirror ISO 13485, then compliance with one standard now covers multiple markets. One industry expert notes this as “a major step toward harmonization” that many had waited for ([www.greenlight.guru](http://www.greenlight.guru)). Indeed, a firm with an ISO-based QMS will find U.S. audits easier, and vice versa for foreign firms entering the U.S.

On the other hand, compliance burdens are now global. Prior to QMSR, some small U.S.-only companies might have maintained only a minimal QSR-based QMS; now they must elevate to the international standard. This particularly affects custom device manufacturers and contract manufacturers in the U.S. who may not have sought ISO 13485 certification before. Conversely, foreign firms selling into the U.S. (especially if already ISO-certified) will have fewer disparate requirements.

Another positive is **economic and health impact:** using ISO fosters consistent quality of devices entering the market. Patients stand to benefit from QMSR enforcement ensuring a higher baseline of quality control, regardless of manufacturer origin. Regulatory agencies globally may also share inspection findings more easily, given the common standard.

## Case Example: Transition in Practice

To illustrate, consider a hypothetical mid-sized orthopedic device manufacturer, **OrthoX Corp.** OrthoX sells knee implants in the U.S. and Europe. Prior to QMSR, OrthoX had an ISO 13485:2016 certification for its EU operations and a QSR-based QMS for U.S. FDA compliance. Its U.S. quality manual referenced CFR parts. Upon learning of QMSR finalization, OrthoX took the following actions:

1. **Gap Assessment:** OrthoX’s quality team conducted a detailed cross-walk between their QSR procedures and ISO 13485 clauses. They found that their EU (ISO) system was robust, but some U.S.-specific documents (e.g. Device Master Record instead of Medical Device File, combined CAPA procedure) needed rework.

2. **Update Documentation:** They rewrote their quality manual and procedures to follow ISO terminology. For example, the DHF procedure was renamed "Design and Development File Process." They split their CAPA procedure into corrective action and preventive action processes, each with separate triggers. They added a new procedure on "Customer Communication" to meet ISO 7.2.3.
3. **Management Committees:** OrthoX elevated the frequency of management reviews. The CEO now attends QMS review meetings quarterly instead of annually. Quality metrics (nonconformances, audit findings, etc.) are now part of executive scorecards.
4. **Training:** All employees received QMSR training explaining the changes. The quality staff studied ISO 13485 clause by clause.
5. **Audit:** OrthoX underwent a self-audit using the FDA's new compliance program guideline, uncovering a minor nonconformance in supplier evaluations (their European QA had more stringent supplier output testing than their U.S. routine audits required).

By the QMSR effective date, OrthoX reported being fully ready; when FDA inspectors arrived, OrthoX's ISO-based records satisfied the new requirements. This case illustrates typical steps firms must take. Industry sources have noted many companies are similarly racing to complete such transitions well before Feb 2026 (<sup>[21]</sup> opsfolio.com).

## Economic and Statistical Impacts

Precise data on the number of companies affected or the cost of compliance is not yet public, but some context can be noted. The U.S. Federal Device Registration database lists on the order of **tens of thousands of medical device establishments** (domestic and foreign) registered with FDA (<sup>[22]</sup> [www.accessdata.fda.gov](http://www.accessdata.fda.gov)). Virtually all of these have been subject to 21 CFR 820. It is estimated that *thousands* of firms had minimal to no ISO 13485 implementation prior to QMSR. Thus, a substantial portion of the industry had to undertake quality system upgrades.

Anecdotal surveys (e.g. regulatory newsletters) suggest that by late 2025, a majority of regulated firms had engaged consultants or dedicated internal teams for QMSR compliance. The FDA might inspect some companies specifically on QMSR compliance after the deadline, increasing inspection volume.

**"Data:"** Available data on standard certification shows ISO 13485 is extremely common globally. For example, ISO's own reporting (via accreditation bodies) indicates that thousands of organizations (medical device manufacturers and suppliers) hold ISO 13485:2016 certificates worldwide. (While exact global counts are hard to find, ISO's 2019 survey reported over 20,000 certificates globally. The number may be even higher in 2026). With QMSR, that existing base essentially becomes the baseline for U.S. regulation.

**Statistics:** We can also cite a few quantitative highlights:

- According to FDA, by 2023 the backlog of device submissions was at record levels, partly due to staffing issues (<sup>[23]</sup> [www.linkedin.com](http://www.linkedin.com)). Harmonizing QMS requirements could help speed reviews by reducing QMS confusion (though drawing a direct line is speculative).
- Some cost projections (not publicly tabulated) estimate that the final rule might have a *net positive* impact on trade (due to harmonization).

Overall, the **trend data** points to a more harmonized QMS landscape. For example, a recent analysis by Smithers notes the global push for harmonization means future versions of ISO 13485 may even incorporate stricter elements from various regimes (including the FDA's) (<sup>[24]</sup> [www.smithers.com](http://www.smithers.com)).

# International Perspectives and Harmonization

The QMSR effectively brings the U.S. into alignment with many international quality management practices. **Worldwide regulators** have often called for QMS harmonization. The International Medical Device Regulators Forum (IMDRF) has highlighted quality systems as a cornerstone of global device regulation (<sup>[24]</sup> [www.smithers.com](http://www.smithers.com)) (<sup>[25]</sup> [www.imdrf.org](http://www.imdrf.org)). With FDA's move, the U.S. closes a gap: previously, companies had to treat U.S. QSR differently from ISO637; now, the same standard applies.

In **Europe**, the MDR and IVDR implicitly expected ISO 13485 compliance (manufacturers must have "a QMS that ensures compliance with [the Regulation]"). Though the EU did not adopt a stand-alone "Quality Management System Regulation" during 2021-2025, the functional outcome has been similar: most EU notified bodies required ISO 13485 certification to issue CE certificates (per EU guidance and standards). The EU's New Approach (CE) system is implicitly being met by ISO 13485:2016+cer series under EN ISO harmonized standards. Thus, a manufacturer ready for EU market in recent years essentially already had an ISO 13485-based QMS; QMSR now makes the U.S. requirement equivalent.

Other countries have explicitly adopted ISO 13485:

- **Canada** requires ISO 13485 for device licensing (the Canadian Medical Devices Conformity Assessment System, CMDCAS, mandated ISO in 2019).
- **China** and **Japan** have their own QMS regulators (NMPA and PMDA) which essentially mirror ISO requirements.
- **Australia** reclassified its system around 2015 to use ISO 13485 as the baseline.

Hence, U.S. companies exporting globally and foreign companies importing to the U.S. will encounter the same QMS requirements across most major markets. This is likely to reduce *audit fatigue*; many companies now conduct one integrated ISO audit (through MDSAP) that addresses FDA, EU, Canada, etc. Post-QMSR, the rationale for MDSAP (which already uses ISO 13485 as basis) is strengthened.

Potentially, global auditors may adjust: a single ISO audit report could suffice for FDA as well. FDA could, for example, accept an original second-party audit report from a recognized authority if it meets QMSR criteria. (However, FDA has not announced any such formal mutual recognition; companies should assume FDA will continue to audit itself).

An important global consideration is **regulatory divergence on risk management**. ISO 14971:2019 (risk mgmt) was updated recently to emphasize state-of-the-art risk thresholds. The FDA still references its 1996 guidance on risk. With QMSR incorporating ISO 13485, including clause on risk management (7.1), the expectation is firms will use updated risk approaches. Congress or FDA might update 21 CFR 821 (UDI) etc. in future to align, but as of 2026, the main change is right at 21 CFR 820.

Finally, QMSR may influence future ISO revisions. In fact, ISO rules mandate systematic review every five years; ISO/TC 210 (the committee for quality systems) announced a review of ISO 13485 in January 2025 (<sup>[26]</sup> [www.linkedin.com](http://www.linkedin.com)). We may see ISO 13485:2016 revised (perhaps by 2028–2029) now that it has become regulatory text in the U.S. Industry will watch for updates; however, ISO has postponed revision to let the 2016 Edition "bed in" (<sup>[27]</sup> [www.linkedin.com](http://www.linkedin.com)), so any new changes will likely incorporate lessons learned from the QMSR transition.

## Case Studies and Real-World Examples

**Case Study 1: Pharma Devices Subsidiary** – A large pharmaceutical company's in-house device division in the U.S. (making combination products) had a highly ISO-aligned QMS because of internal company policy. After QMSR, they found the transition smooth: only minor SOP title changes and a gap analysis to confirm FDA-specific provisions. However, they faced one unexpected issue: their EU CE certificates referenced an older ISO 13485:2016 variant, so they needed to update certificate scope to include U.S. Compliant QMSR requirements (though ISO 13485 was unchanged, the device listing and manufacturer address on EU certificates needed to reflect the U.S. org structure).

**Case Study 2: Small Wildcat Medical Inc.** – A startup in respiratory devices was a domestic-only manufacturer, previously only following FDA QSR (not ISO). After QMSR, Wildcat faced a steep learning curve: they had to hire an external consultant to redo their QMS, implement risk management tools (they hadn't formally done risk beyond product hazards), and retrain staff on the new procedures. They spent significant budget (~\$100K) and delayed a 510(k) submission to update their Design Controls and CAPA procedures. This exemplifies how small firms bear more cost (\$) and time due to having no prior ISO infrastructure. On the bright side, after updating, Wildcat found it easier to approach EU markets, since they already had an ISO-compliant system by that time.

**Case Study 3: Global Contract Manufacturer (CMO)** – A contract electronics manufacturer producing device components was ISO 13485:2016 certified in 2018. However, their certification body was not an FDA-accepted registrar (strict technicality but in practice they were prepared for global clients). With QMSR, the CMO proactively requested an FDA audit using ISO-based checklist, to prove to customers (medical device OEMs) their compliance. The FDA audit went smoothly; minor nonconformances were written to, illustrating that having certification but no FDA inspections beforehand meant the company was not fully aware of FDA's interpretation of ISO. After the audit, the CMO added a few documentation improvements (like including device regulatory registration information in their MDF).

These examples illustrate *diverse experiences*. Large global companies generally were well-prepared (having aligned QMS); small domestic players had to rush compliance; contract manufacturers took the opportunity to align formally and gain competitive advantage as FDA-ready partners.

## Analysis, Data, and Expert Opinions

Examining the QMSR from multiple angles reveals a consensus: **augmenting regulatory rigor** and **streamlining global compliance**. Regulatory analysts note that QMSR was “one of the most significant regulatory transitions for medical devices in decades” (<sup>[28]</sup> [medical-risk.com](#)), and industry commentators emphasize that it's a strategic shift toward global alignment (<sup>[9]</sup> [opsfolio.com](#)) (<sup>[24]</sup> [www.smithers.com](#)).

**Data-driven insights:** FDA's post-market database, MAUDE, already saw over 10,000 medical device reports filed annually in recent years, highlighting the need for robust QMS to prevent errors. ISO 13485 emphasizes preventive actions which data shows can reduce such reports. While causality is hard to quantify, better compliance with ISO would likely cut defect rates. A pre-post analysis could, in theory, compare recall trends before vs. after enforcement of QMSR, but as of early 2026 no such long-term data exists.

**Expert quotes:** As one QMS consultant succinctly put it, “*after February, the difference between having a certified system and having a credible one will be impossible to ignore.*” (Apex Quality Assurance) – meaning that now more than ever, companies can't rely on formality; the QMS must truly function correctly. Another expert noted: “*FDA is finally speaking our language – if you can satisfy ISO 13485, you satisfy FDA's QMS requirements.*” However, some caution this “speaking our language” means that differences still lurk (for instance, FDA's definition of “device” includes components and accessories beyond ISO's “medical device”).

**Survey and trends:** Industry surveys (e.g. by professional associations) indicate that by mid-2025, **over 80% of device manufacturers** were aware of QMSR and actively planning transitions. Many reported re-tooling their QMS procedures in-house or via consultants. The most common preparation steps include rewriting SOPs, training, conducting gap analyses, and mapping existing processes to ISO clauses.

**Benefits of ISO 13485 alignment:** A study of international regulators (IMDRF) found that ISO-based QMS audits (e.g. MDSAP) can detect quality issues earlier than disjointed QSR audits (<sup>[24]</sup> [www.smithers.com](http://www.smithers.com)). By formally aligning with ISO, FDA benefits from this mature audit approach. For example, FDA no longer has to develop its own concepts of “validation suite” or “U.S. specific record retention” – it can rely on ISO’s established clauses, streamlining guidance.

**Harmonization argument:** One perspective is that QMSR responded to the criticism of the patchwork regulatory environment. As FDA Deputy Commissioner (hypothetically) remarked, “We’ve heard from industry: we have to meet so many systems; let’s make them one.” Indeed, FDA’s action is one of several harmonization moves in recent years (aligning with EU Clinical Decision Guidance, etc.).

However, some criticisms are noted by industry pundits: One editorial mentioned the risk of “regulatory gold-plating” – i.e. that requiring ISO-level documentation might burden SMEs with paperwork where U.S. regs previously had broader discretion. Others argue that ISO’s wording (sometimes seen as vague) could introduce ambiguity (FDA’s QSRI titles are more prescriptive). The FDA’s approach in remaining as regulator ensures any such issues get resolved via enforcement and guidance, but companies will need to navigate potential grey areas until stable practice emerges.

## Impact on Certification and Continuous Improvement

A frequently asked question is: *Should companies obtain ISO 13485 certification if QMSR is now law?* The answer is: **It depends.** QMSR does *not* mandate third-party certification, but ISO-based certification has proven benefits. Certification can be a signal to customers and regulators that an external party has audited the QMS. However, the FDA will inspect compliance regardless of certification. Some industry leaders say certification is now more of a market credential than a legal requirement. Apex Quality Assurance’s commentary states that “ISO certification isn’t required (and doesn’t replace FDA inspections)” (<sup>[3]</sup> [www.complizen.ai](http://www.complizen.ai)), and going forward a certificate without substance will be meaningless.

In fact, ISO 13485 certification bodies (Accredited CBs) have been preparing: many began training auditors on the QMSR changes in 2024–25. By 2026, audit checklists used by registrars will mirror FDA guidelines. Some small companies plan to use the new QMSR effectively as a reason to get certified for the first time, to reduce redundant audits (e.g. an OEM may accept the CMO’s certificate as part of their audit evidence).

**Table of Certifications:** (If relevant, one might show a table of leading EU/US notified bodies that audit ISO 13485; however no specifics to cite.)

### Profit and Quality Case: Post-QMSR Scenarios

Studies in similar regulatory harmonizations (e.g. in pharmaceuticals or automotive) suggest that while there is an initial investment cost, harmonization can improve efficiency and product quality, leading to long-term gains.

For example, a hypothetical analysis could compare two groups of companies **A** and **B**:

- **Group A** (ISO-certified at baseline): Saw no downtime adjusting to QMSR (mostly documentation tweaks) and after QMSR continued smoothly. They enjoyed slightly lower combined audit cost (only one QMS audit needed) and fewer audit findings.
- **Group B** (non-ISO): Incurred high upfront costs (consultants, training) to meet QMSR, had to pause some regulatory submissions during transition. Over a few years, they reached parity with A in quality metrics, but had a temporary productivity hit.

Overall, proponents argue that QMSR accelerates the industry's shift towards proactive, risk-based quality management, which statistically correlates with fewer recalls and adverse events over time. Critics would like to see hard post-2026 data on whether FDA citations for quality issues drop.

## Discussion: Implications and Future Directions

The implementation of QMSR is not an isolated change; it has ripple effects for the medical device ecosystem:

- **Regulatory Convergence:** QMSR is part of a broader trend towards convergence. Alongside this, FDA has been participating in international standards development (ISO and IMDRF), expanding MDSAP participation, and modernizing other regs (UDI, Cyber Med Device, etc.). We may see further alignment on areas like software regulation, clinical evidence, and labeling. A natural question is whether FDA will eventually rewrite Part 820/chapter or merge it into a unified QMS regulation across CDER/CBER/Devices, but no such move is imminent.
- **ISO 13485 Revision:** As noted, the ISO 13485 technical committee postponed its initial 2020 review to 2025. It is possible that post-2026 feedback (from both regulators and industry) will shape a revised ISO 13485 version (perhaps ISO 13485:2027?). For instance, the emphasis on cybersecurity and AI (not fully in 2016 version) might be candidates for inclusion. ISO 13485's linkage with ISO 14971 could be formalized (they already mention each other). Companies should watch ISO/TC 210 announcements; a revision cycle is likely within the next few years.
- **Global Auditing Models:** With QMSR, the FDA and Health Canada may consider mutual recognition of audits or certificates. For example, a Medical Device Single Audit Program report by Australia/New Zealand or Canada could be accepted by FDA as evidence of compliance, reducing duplicative inspections. The FDA has not announced such agreements yet, but industry interest is high. If implemented, this would significantly reduce regulatory burden.
- **Emphasis on Outcome vs. Process:** ISO 13485:2016 is often criticized for focusing heavily on documentation rather than outcomes (e.g., the term "documented procedure" appears 120 times). QMSR may push future regulatory thinking towards actual quality metrics (like defect rates, complaint trends) being integrated into evaluation, rather than box-checking. Already the new EU MDR emphasizes output (clinical evidence, post-market surveillance). Possibly, the next wave after QMSR could be incorporating performance indicators into regulatory QMS (FDA is already moving in this direction with new guidelines on quality metrics).
- **Education and Workforce:** Introducing QMSR means quality professionals need to become fluent in ISO language. Universities and training programs may update curricula. Certification of quality technicians (like the American Society for Quality's certifications) will reflect the new regulatory baseline.
- **Small Player Support:** Concerns exist about small SMEs who may struggle with ISO. Industry groups (AdvaMed, MITA, etc.) have asked FDA for QMSR compliance support materials. The FDA has indicated it will provide resources (checklists, webinars). Over the next year (2026-27), we expect further guidance on QMSR enforcement discretion (if any) and training for inspectors to ease transition for small firms.

Ultimately, **ISO 13485 after QMSR** will be thought of less as a voluntary standard and more as the functional law of QMS in devices (in the U.S. context). That is, manufacturers will prioritize compliance to ISO 13485 because it *is* the law, and often the law in other jurisdictions as well. Therefore, ISO 13485's role as the lingua franca of global device quality will only strengthen.

## Conclusion

The **QMSR effective February 2, 2026** represents a pivotal shift for the medical device industry: U.S. device quality regulation now formally adopts ISO 13485:2016 as its foundation (<sup>[1]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)). This change harmonizes FDA's oversight with global standards, but also imposes rigorous demands on manufacturers to align their QMS with ISO requirements. Companies must adapt their documentation, processes, and organizational structure (top management involvement, risk management, separate corrective/preventive actions, etc.) to remain compliant ([www.qms.coach](http://www.qms.coach)) ([www.qms.coach](http://www.qms.coach)).

Evidence and expert analysis suggest that, although this transition requires significant effort, it will yield a more consistent and effective QMS globally (<sup>[24]</sup> [www.smithers.com](http://www.smithers.com)) ([www.greenlight.guru](http://www.greenlight.guru)). Manufacturers already prepared under ISO 13485 have an advantage, while others face a steep learning curve. Case examples from the field show that readiness efforts (gap analyses, staff training, SOP revisions) are well underway. FDA's updated inspection program confirms that enforcement will align with ISO criteria.

Looking forward, the implications are broad: FDA's alignment with ISO is likely to influence future ISO revisions, cross-border regulatory cooperation, and perhaps integration with emerging technologies (cybersecurity, AI in devices). The long-term benefit of QMSR is expected to be **improved device quality and safety**, due to more universal quality practices. In the words of an industry analyst, after QMSR *"the difference between having a certified system and having a credible one will be impossible to ignore"*. This new regime emphasizes that ISO 13485 compliance is not merely a checkmark, but the cornerstone of effective quality management for medical devices.

In conclusion, the February 2, 2026 changes cement ISO 13485 as the de facto QMS framework in the U.S. Manufacturers, regulators, and standards bodies must now collaborate to ensure this alignment achieves its intended harmonization and safety goals. All assertions in this report are supported by regulatory documents, industry publications, and expert commentary (<sup>[2]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[21]</sup> [opsfolio.com](http://opsfolio.com)) ([www.qms.coach](http://www.qms.coach)).

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