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FDA QMSR: Internal Audit Reports Now Open to FDA Inspection

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Executive Summary

The U.S. Food and Drug Administration's (FDA's) **Quality Management System Regulation (QMSR)** has replaced the long-standing **Quality System Regulation (QSR)** (21 CFR Part 820) as of February 2, 2026 (www.fda.gov) (www.seleon.com). This landmark rule aligns U.S. device quality requirements with the international ISO 13485:2016 standard (www.fda.gov) (www.cognidox.com). One of the most significant changes under QMSR is that **internal audit and management review records, which were previously exempt from FDA inspection, are now subject to inspection** (www.fda.gov) (www.cognidox.com). In other words, companies can no longer consider internal audit reports "confidential" with respect to FDA, since §820.180(c)'s previous exemptions have been eliminated (www.fda.gov). This shift dramatically increases regulatory transparency: FDA inspectors may now request and review quality audit reports, supplier audit reports, and management review data as part of any device inspection.

This comprehensive report examines the background, current state, and implications of the QSR-to-QMSR transition, with an emphasis on the new treatment of internal audit reports. It covers the historical context and FDA rulemaking, details the substantive changes under QMSR (including ISO harmonization and new compliance expectations), and analyzes the impact on industry. The report includes evidence from official FDA guidance and credible analyses (www.fda.gov) (www.cognidox.com) (www.fda.gov), incorporates case scenarios illustrating practical effects on device firms, and discusses future directions. Supported by tables and figures, the analysis emphasizes how companies must adapt their quality systems — particularly audit and record-keeping processes — in light of the new regulation.

Introduction and Background

The **Quality System Regulation (QSR)**, codified at 21 CFR Part 820, was published in October 1996 (effective June 1, 1997) to govern the Current Good Manufacturing Practice (CGMP) for medical devices (www.seleon.com). It replaced earlier device cGMP rules from 1978 under the FDA's statutory authority (FD&C Act § 520(f)) and introduced requirements for design controls, production, corrective/preventive actions, and quality auditing (www.seleon.com). Since 1996, Part 820 (often called the "QS Regulation") had remained essentially unchanged (www.seleon.com), even as global device Quality Management System (QMS) standards evolved. In parallel, the ISO 13485 standard (first issued in 1996 and revised 2003/2016) became the flagship international QMS for medical devices. By 2016, ISO 13485 had been widely adopted by regulators worldwide (www.seleon.com) (www.seleon.com).

Given this landscape, the FDA initiated formal harmonization. In February 2024, the FDA published a **Final Rule** amending Part 820 by incorporating the requirements of ISO 13485:2016 by reference (www.fda.gov) (www.cognidox.com). This rule effectively *renames* Part 820 as the **Quality Management System Regulation (QMSR)** and mandates ISO-aligned practices (while preserving critical FDA-specific requirements) (www.fda.gov) (www.cognidox.com). The two-year transition period (from February 2024 to Feb. 2, 2026) was chosen to allow manufacturers to align with the new requirements (www.seleon.com) (www.cognidox.com). As a result, on February 2, 2026, the "old" QSR yielded to QMSR (www.fda.gov) (www.seleon.com).

The FDA's stated objectives for the QMSR include **regulatory harmonization and simplification**. In its rulemaking, the Agency emphasized that aligning with ISO 13485 promotes global consistency and reduces burden on manufacturers, thereby improving patient access to quality devices (www.cognidox.com). Indeed, as one analysis notes, the FDA believed that retaining dissimilar QMS rules would "hinder efficiency and limit patient choices," so the new rule aims for "regulatory simplicity and global harmonization" expecting to reduce industry burden (www.cognidox.com). In practice, QMSR does two key things: it adopts ISO's terminology and quality management concepts (risk-based thinking, leadership accountability, etc.) and it **removes outdated provisions** (or adds clarifications) to spell out explicitly things that in practice already occurred. In sum, the QMSR aligns the U.S. system with international norms while clarifying FDA's expectations.

The following sections examine the QSR (pre-2026) and QMSR (post-2026) requirements in detail, with a special focus on **internal audits and related records**, which are now subject to regulatory inspection.

Key Changes: From QSR to QMSR

The QMSR final rule amends 21 CFR 820 in several important ways. Table 1 below summarizes some of the major high-level differences:

Aspect	Under QSR (pre-2026)	Under QMSR (post-2026)
Regulation Title	Title "Quality System Regulation (QSR)" (www.fda.gov) (21 CFR 820)	Renamed "Quality Management System Regulation (QMSR)"(www.fda.gov)
ISO Alignment	Discussed but not incorporated; some requirements differ from ISO	ISO 13485:2016 requirements **incorporated by reference** (www.fda.gov)
Core Philosophy	Traditional GMP/QS approach; risk often implied	Explicit **risk-based** and preventive focus (new risk management clauses) (www.cognidox.com)
Terminology (Mgmt.)	"Management with executive responsibility" (www.cognidox.com)	Now "Top management" (consistent with ISO) (www.cognidox.com)
Inspection Process	FDA used the Quality System Inspection Technique (QSIT)	QSIT replaced by new Compliance Program (CP 7382.850) (www.fda.gov)
Incorporated Requirements	Standalone U.S. regulations (21 CFR 820)	Incorporates all applicable ISO 13485:2016 requirements (www.fda.gov)
Design / General Provisions	As QSR (design controls, etc.)	Design and development requirements come from ISO 13485 Clause 7.3 for class II, class III and listed class I devices (§820.10(c)) (www.ecfr.gov)
Document Control (820.40)	Basic doc control	Document control under ISO 13485 Clause 4.2.4; new §820.35 adds record-content requirements (www.seleon.com)
Purchasing / Supplier (820.50)	QSR-based controls	New emphasis on supplier QMS, including supplier audit expectations
Device Master Record (DMR)	Required under QSR	Replaced by "Medical Device File" concept (ISO term) (www.cognidox.com)

Aspect	Under QSR (pre-2026)	Under QMSR (post-2026)
Labels/Packaging	Minimal detail in QSR	New §820.45 requires detailed labeling/packaging procedures, including UDI, shelf life, instructions (www.cognidox.com)
Records Exempt from FDA Inspection	**Exempt**: Internal audits, management review records, supplier audits per 820.180(c) / QSIT (www.fda.gov)	**No exempt**: FDA **can inspect** internal audits, management reviews, supplier audit reports (www.fda.gov)
Summary of Approach	U.S.-centered QMS with heavier emphasis on corrective action culture	Harmonized with international practice; emphasizes prevention and documentation of risk

Table 1: Key differences between the legacy QSR and the new QMSR. (Sources: FDA QMSR Final Rule and analyses (www.fda.gov) (www.seleon.com).)

A few points on Table 1 are highlighted by regulators and industry experts. First, as noted above, the **title** and structure have changed to slot in ISO references (for example, QMSR explicitly references ISO 13485 clauses in lieu of many bare FDA requirements (www.cognidox.com)). The **inclusion of risk-based thinking** is a big shift in emphasis: while the old QSR had no explicit risk management clause, QMSR incorporates ISO 13485's risk-based requirements (for example, the risk management requirements of Clause 7.1) into 21 CFR 820 by reference (www.cognidox.com). Management semantics have changed too, elevating leadership responsibility – ISO speaks of "top management" and QMSR follows suit (www.cognidox.com).

Critically, the **inspection and records provisions** have been revised. FDA will no longer use the old QSIT inspection model as of Feb. 2026 (www.fda.gov). Instead, a new inspection framework (CP 7382.850) will be employed, one that fully integrates QMSR requirements (FDA has also said it will train its own staff on the change (www.fda.gov) (www.seleon.com)). Equally important is **how record-keeping requirements are handled**. Under QSR, 21 CFR 820.180(c) **exempted several records from FDA oversight** – namely the reports of management reviews, internal quality audits and supplier audits (FDA could instead ask management to certify in writing that these reviews and audits had been performed and documented). These reports were therefore not subject to routine inspection (www.fda.gov). Under QMSR, however, the agency explicitly **eliminated these exemptions** (www.fda.gov). As FDA's QMSR FAQ states:

> *"Yes. The QMSR gives the FDA the authority to inspect management review, quality audits, and supplier audit reports. The exceptions that existed in the QS regulation at §820.180(c) are not maintained in the QMSR. … These records are maintained in the regular course of business and should be readily available upon inspection."* (www.fda.gov).

In plain terms, **internal audit reports can now be inspected by FDA**, and thus are no longer off-limits. (FDA notes that manufacturers already share these reports with other regulators, so the change is more about formalizing access than creating new burden (www.fda.gov).)

Internal Audits and Record Confidentiality

Internal quality audits have long been a cornerstone of device QMS, required by 21 CFR 820.22 (each manufacturer must conduct periodic audits of the quality system). Under legacy QSR, these audit **reports were considered confidential** from the standpoint of FDA inspections. Specifically, §820.180(c) given *under QSR* categorized quality audit records (and management review minutes) as *excluded* from FDA review, meaning inspectors would not normally request them (www.fda.gov). In practice, if an audit uncovered issues, the firm could document CAPA records without turning over the underlying audit file.

However, the **QMSR abolishes that safe harbor**. Starting Feb. 2, 2026, FDA officials may ask to see the actual internal audit documentation. The Agency has said that management review, quality audit and supplier audit reports “are maintained in the regular course of business and should be readily available upon inspection” (www.fda.gov). Thus, the content of internal audits is effectively open to regulatory review. In consequences, internal audits “are no longer confidential” in the regulatory sense: companies cannot assume the reports will be kept private from FDA review.

This rule change has several implications. From FDA’s perspective, it fills a historical blind spot: inspectors can directly confirm whether audits found any nonconformities and if appropriate corrections were tracked. It also harmonizes to global practice: other regulators (and certifying bodies under ISO/MDSAP) already view audit records as part of the official QMS documentation, so this aligns FDA with international norms (www.cognidox.com). Finally, FDA has kept its clarification that records it receives are protected under **21 CFR Part 20** even though they are no longer exempt, and new §820.35(d) lets manufacturers mark records they deem confidential to aid FDA’s disclosure decisions (www.cognidox.com). In short, audit reports will be visible to FDA but protected under agency confidentiality rules thereafter.

For device firms, removing the confidentiality shield means **greater transparency and risk**. Now, any adverse findings or strategic observations captured in an internal audit could be questioned by FDA. For example, if an audit uncovered a recurring process deviation, the Agency will be able to scrutinize how management addressed it, rather than relying solely on the company’s CAPA summary. Manufacturers should therefore write internal audit reports knowing they may be reviewed by regulators (www.cognidox.com). On the other hand, the change may foster stricter compliance, since audit and management review findings are now visible to FDA inspectors. Either way, the changed treatment underscores that audit reports can have regulatory impact.

Case Study: *XYZ Medical Devices (hypothetical)* conducted a thorough internal audit of its injection pump line in mid-2026. The audit report revealed minor nonconformances in batch record review and calibration procedures, with planned CAPAs noted. Under the pre-QMSR regime, FDA inspectors (in a follow-up visit) might not have seen the full audit report – only CAPA closure records – because audit files were exempt. Under QMSR, the next inspection *entitles* FDA to demand the actual audit logs. The inspectors obtain the report and see exactly what was found and decided. If they judge a CAPA was delayed or inadequate, they may cite a violation directly – all revealed by an originally internal report. This scenario (though contrived) illustrates how QMSR erases the former “private” status of audit findings.

Another angle involves **supplier audits**. Many firms have supplier quality audit programs (auditing component vendors, contract manufacturers, etc.). Such supplier audit reports were also considered “internal” by nature. QMSR similarly authorizes FDA to inspect supplier audit records, thus extending transparency to the supply chain. Device consultants now advise companies to maintain thorough documentation of such audits, as FDA can request them for review.

Scale of the change: Detailed industry surveys on QMSR readiness are only emerging. What is clear is that the QMSR applies to every manufacturer subject to Part 820, and that firms already operating an ISO 13485-based QMS start from a common baseline (www.cognidox.com) (www.seleon.com). FDA itself notes that manufacturers already provide management review, quality audit and supplier audit reports to other regulators, so making them available to FDA inspectors should not add burden (www.fda.gov).

The effect on enforcement remains to be seen. With audit reports open to inspection, FDA Form 483 observations could reference internal audit findings directly. This is speculative; FDA has said it will train its staff and engage stakeholders on the change (www.fda.gov).

Incorporating QMSR: Industry Perspectives and Case Examples

Manufacturer Viewpoint: Many medical device companies have already aligned their QMS with ISO 13485 for EU CE marking or MDSAP. From their perspective, the QMSR change is a natural extension – a harmonization rather than a revolution, as industry authors note (www.seleon.com). Industry commentary observes that FDA’s existing approach to quality requirements is largely preserved, with ISO 13485 now providing the framework (www.seleon.com). In practice, companies using ISO-based systems may need only modest adjustments (e.g. renaming documents, adding a risk clause, updating forms). Many see the clear benefit of avoiding dual-documentation for ISO vs. FDA.

However, even well-prepared firms acknowledge challenges. The removal of audit exemptions is one such challenge. Audit managers must train internal auditors that findings could be scrutinized by FDA. Documentation practices may need tightening: for instance, ensuring audit follow-up is evident in records. Some quality leaders worry that auditors might become “less blunt” in reporting issues, fearing regulatory fallout. Others see the change positively, as it forces management to take audit findings more seriously, knowing FDA can verify compliance. In any case, industry consultants advise firms to **review their audit and review procedures** now. This includes formally including audit reports in inspection readiness checklists.

Regulatory/Legal Perspective: For regulators and legal experts, the QMSR’s treatment of audits is part of broader transparency. The FDA FAQ states that since manufacturers are required to provide such documents to other regulators, making them available to FDA inspectors is not an additional burden (www.fda.gov). In effect, the Agency has closed a gap in its inspection access. (Notably, FDA continues to protect records adequately once obtained: Part 20 confidentiality rules apply (www.cognidox.com).) Companies should anticipate closer scrutiny of audit findings and keep evidence of how follow-up actions were tracked.

Implications and Future Directions

The shift from QSR to QMSR heralds broader implications for quality culture and future regulation:

- **Inspection Paradigm:** The withdrawal of QSIT and introduction of CP 7382.850 means FDA inspectors have new checklists and expectations (www.fda.gov) (www.fda.gov). Inspection teams will likely place more emphasis on process effectiveness (risk management, trending data) rather than just prescriptive checks. Firms should train their teams on the QMSR-focused inspection scope.
- **Transparency and FOIA:** With audit reports accessible to FDA, the potential for public disclosure via FOIA exists. While patient safety drives transparency, manufacturers worry about proprietary information in audits. The FDA maintains that inspected records will remain confidential, but FOIA requests (as part of any disclosure of inspection records) could reach some content. Companies may need legal strategies to protect truly proprietary technical information, even as complying with audit access.
- **Cultural Shift:** QMSR reinforces the idea of *quality as culture*. By insisting "top management" be visibly engaged and by making audits "inspectable," the rule signals that FDA views QMS as part of normal business transparency. Industry commentators suggest this could lead to a stronger quality culture – i.e. devices are safer when companies know regulators see inside their processes (www.cognidox.com) (www.seleon.com).
- **Global Harmonization:** Because ISO 13485 forms the regulatory baseline, device manufacturers that sell globally may find it easier to align operations. In fact, U.S. companies certified to ISO 13485 (or audited under MDSAP) should have less incremental work. Firms that only had QSR/GMP systems may now feel pressure to adopt ISO-style practices wholesale. This convergence also aids FDA's bilateral recognition efforts: in the future, FDA inspections and MDSAP audits may be more interchangeable as they cover the same essential requirements.
- **Future Rulemaking:** The QMSR preamble and FAQs emphasize that future ISO revisions would be handled via notice-and-comment rulemaking (www.fda.gov) (www.seleon.com). Thus, the QMSR is not static: as ISO evolves, FDA intends to update Part 820 accordingly. With the QMSR in force since February 2, 2026, the immediate task for industry is to keep its quality system compliant under the new rule.

Tables: Documents and Requirements Comparison

To summarize some key points, the tables below compare affected document types and regulation features.

Table 2 – Inspection Access to Quality Records (QSR vs. QMSR):

Record/Report Type	QSR (21 CFR 820 pre-2026)	QMSR (21 CFR 820 post-2026)
Internal Quality Audit Reports	Exempt from FDA inspection under 820.180(c) (not typically reviewed) (www.fda.gov)	**Accessible** – FDA may inspect audit reports; QMSR removes exemption (www.fda.gov)
Management Review Minutes/Reports	Exempt under 820.180(c) (www.fda.gov)	**Accessible** – FDA may review management review outputs (www.fda.gov)
Supplier Audit Reports	Exempt from FDA inspection under 820.180(c)	**Accessible** – Specifically included in QMSR inspection authority (www.fda.gov)
Calibration/Test Method Records	Not exempt; reviewable by FDA (§820.72)	Reviewable by FDA (ISO 13485 Clause 7.6)
Device Master Record (DMR)	Required and reviewable by FDA	Replaced by “Medical Device File”; still reviewable by FDA
Device History Record (DHR)	FDA-inspected routine quality record	DHR term dropped; production records under ISO 13485 remain required and inspectable
Complaint Files	Required and inspected (820.198)	Inspectable; ISO 13485 Clause 8.2.2 plus complaint record content in §820.35(a) (www.ecfr.gov)
Supplier Control Documents	Contained in purchasing records; focus on selection controls	Emphasized under ISO alignment; FDA expects documentation

Table 2: Status of various quality system records under the old QSR and new QMSR. Now internal/supplier audit documents are explicitly inspectable (www.fda.gov), whereas previously they were held “off-limits.”

Table 3 – Select 21 CFR 820 (QSR) vs. QMSR Changes:

CFR Section/Subpart	QSR Requirement (Pre-2026)	QMSR Requirement (Post-2026)
§820.3 *Definitions*	Definitions, including “customer” and DMR terms	Most QSR definitions replaced by ISO 13485 terms; “customer” covers internal and external recipients (www.cognidox.com)
§820.20 *Management Responsibility*	Quality policy, org. chart, management reviews; “management with executive responsibility” (www.seleon.com)	Section reserved; ISO 13485 Clause 5 applies, with “top management” (www.cognidox.com)
§820.22 *Quality Audits*	Establish audit procedures; conduct internal quality audits	Section reserved; internal audits under ISO 13485 Clause 8.2.4, and audit reports are now inspectable (previously exempt) (www.fda.gov)
§820.25 *Personnel*	Competency, training records required	Section reserved; ISO 13485 Clause 6.2 applies
§820.30 *Design Controls*	Design controls for class II, class III and listed class I devices	Section reserved; ISO 13485 Clause 7.3 applies to the same device classes (§820.10(c))
§820.35 *Control of Records*	No such section (records were in Subpart M)	**New Section** adding record content for complaints, servicing and UDI; §820.35(d) lets manufacturers mark confidential records for Part 20 disclosure decisions (www.cognidox.com)
§820.45 *Labeling/Packaging*	(previously under Subpart K, limited mention)	**New Section** for detailed label/packaging controls (UDIs, expiration, instructions) (www.cognidox.com)

CFR Section/Subpart	QSR Requirement (Pre-2026)	QMSR Requirement (Post-2026)
§820.100 *CAPA*	CAPA procedures, verification	Section reserved; ISO 13485 Clauses 8.5.2 and 8.5.3 apply
Subpart M *Records* (§820.180)	General requirements; certain records exempt	Subpart reserved; exemptions removed and records requirements come from ISO 13485 plus §820.35 (www.fda.gov)
Subpart I *Nonconforming Prod.*	Control and disposition	Subpart reserved; ISO 13485 Clause 8.3 applies
Various	Referenced “Device Master Record”	Such references replaced by “Medical Device File” (www.cognidox.com)

Table 3: Examples of specific changes in CFR Part 820 from QSR to QMSR. (Sources: FDA final rule and QMSR guidance (www.fda.gov) (www.cognidox.com).)

Conclusion

The transition from the Quality System Regulation to the Quality Management System Regulation marks a major evolution in U.S. medical device oversight. By formally aligning 21 CFR 820 with ISO 13485, the FDA is signaling an “internationalization” of U.S. device GMPs (www.cognidox.com) (www.seleon.com). For manufacturers, this harmonization means that much of the quality system they may already have in place for global markets will satisfy U.S. law — but with important caveats. In particular, internal audit and management review processes must now operate under the assumption of FDA transparency. Audit findings, once safely “behind closed doors,” may be disclosed to regulators and, under FOIA, potentially to the public (subject to confidentiality rules) (www.cognidox.com) (www.fda.gov).

As of Feb. 2026, every device maker must be prepared for inspectors to request and review internal audit documentation. Companies should carefully inventory their audit practices, ensure full compliance with new QMSR clauses, and train staff accordingly. Quality leaders will need to stress accurate, verifiable record-keeping, since audit trails may become part of formal regulatory records. At the same time, the QMSR’s emphasis on risk-management and quality culture offers an opportunity to improve device quality upstream, rather than dealing only with the after-effects of problems.

Going forward, the medical device industry should watch for further changes. Future ISO revisions could cascade into CFR updates, and FDA has committed to revisit regulations as needed. Inspection processes, too, may evolve as FDA gains experience under CP 7382.850. In the near term, heightened regulatory scrutiny of internal audits will likely raise the bar for quality compliance. But in the longer view, the shift from QSR to QMSR may help fulfill the FDA’s goal of consistent, high-quality device production aligned with global standards (www.fda.gov) (www.cognidox.com). Companies that embrace transparency and root-cause discipline in their quality cultures will be best positioned for success under the new regime.

References: U.S. FDA (2024) *Quality Management System Regulation – Frequently Asked Questions* (www.fda.gov) (www.fda.gov); FDA Final Rule Documentation (www.fda.gov) (www.seleon.com); Cognidox industry analysis (www.cognidox.com) (www.cognidox.com); Seleon (Germany) regulatory briefing (www.seleon.com) (www.seleon.com); plus trade publications and expert commentaries on QMSR.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://www.fda.gov/medical-devices/quality-management-system-regulation-qmsr/quality-management-system-regulation-frequently-asked-questions
2. https://www.seleon.com/en/part-820-the-fda-is-changing-its-qm-requirements-as-of-2026/
3. https://www.cognidox.com/blog/qmsr-vs-iso13485
4. https://intuitionlabs.ai/articles/qms-ai-ml-medical-devices-guide
5. https://intuitionlabs.ai/articles/biotech-qms-strategy-excel-to-eqms
6. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820

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