

FDA Quality Management System Regulation QMSR Summary on Medical Devices - ISO 13485 Alignment and Changes vs. Prior QSR

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QMSR — Quality Management System Regulation

This is the **new** FDA regulation (effective **February 2, 2026**) that replaces most of the legacy 21 CFR 820. QMSR incorporates **ISO 13485:2016** by reference and adds FDA-specific clarifications.

QSR — Quality System Regulation

This is the **legacy** FDA regulation (21 CFR 820, established in 1997). It defined FDA’s CGMP requirements for medical devices before the 2026 update.

High-level alignment with ISO 13485:2016

Aspect	QMSR (2026)	ISO 13485:2016 relationship
Core requirements	21 CFR 820 now largely incorporates by reference ISO 13485:2016	ISO 13485 is the primary QMS requirements set for devices in the U.S.
Scope	Medical devices; with conforming edits to 21 CFR 4 for combination products	Same medical device QMS scope; QMSR clarifies FDA-specific expectations
Terminology & concepts	Updated to harmonize with ISO 13485 and Clause 3 of ISO 9000:2015	ISO terminology generally used, but FDA definitions prevail where needed
Inspection approach	QSIT retired; new Compliance Program 7382.850 used for inspections	Inspections now assess compliance to ISO 13485 as implemented under QMSR

Key ways QMSR aligns with ISO 13485

- **Incorporation by reference:** **QMSR explicitly incorporates ISO 13485:2016** as the core CGMP/QMS requirements for medical devices. Manufacturers are expected to implement ISO 13485 and, through that, meet FDA CGMP obligations.
- **Substantial similarity determination:** FDA concluded ISO 13485 requirements, taken in totality, are **substantially similar to the legacy QSR**, providing comparable assurance of safety, effectiveness, and compliance.

- **Clarifying additions, not wholesale rewrite:** QMSR adds **FDA-specific clarifications** (e.g., definitions, recordkeeping, certain concepts) to avoid conflicts with other FDA regulations while keeping ISO 13485 as the backbone.
- **Combination products:** Conforming edits to **21 CFR Part 4** clarify how device QMS requirements for combination products map to QMSR/ISO 13485, without changing the underlying CGMP expectations.

Major changes vs. prior Quality System Regulation (legacy 21 CFR 820)

1. Structural shift: from FDA-unique QSR to ISO-based QMSR

- **Before:** Legacy QSR (1997 revision of 21 CFR 820) was an FDA-specific regulation, loosely aligned with ISO 9001/early ISO 13485 but with its own structure and terminology.
- **Now:** QMSR makes ISO 13485:2016 the **formal reference standard**, with 21 CFR 820 functioning as a short regulation that points to ISO 13485 plus FDA-specific additions.

2. Terminology and documentation changes

Examples (not exhaustive, but important for procedures and DMF/technical file language):

- **Device Master Record (DMR)** → aligned with ISO's **Medical Device File (MDF)** concept.
- **CAPA structure:** Legacy QSR treated CAPA as a combined system; ISO 13485 distinguishes **corrective actions** and **preventive actions** more explicitly.
- Broader adoption of ISO terms (e.g., “risk management,” “validation,” “monitoring and measurement”) consistent with ISO 13485 and ISO 9000:2015 Clause 3.

3. Inspection methodology

- **Quality System Inspection Technique (QSIT) retired:** FDA no longer uses QSIT (7382.845) or PMA preapproval/postmarket inspection program 7383.001.
- **New program 7382.850:** Inspections now follow a QMSR-specific compliance program, effectively assessing ISO 13485 implementation plus FDA clarifications.

4. Harmonization and global alignment

- Legacy QSR often required **dual maintenance** of QSR and ISO 13485 systems for global manufacturers.
- Under QMSR, a single ISO 13485-based QMS—appropriately tailored to FDA's added requirements—can serve both U.S. and international markets, reducing redundancy and easing global compliance strategy.

5. Clarified expectations vs. QSR “gaps”

- QMSR uses ISO 13485’s more explicit requirements for **risk-based controls, supplier controls, validation, and postmarket feedback**, areas where QSR was sometimes interpreted more flexibly.
- FDA’s additions ensure alignment with FD&C Act obligations (e.g., records, reporting, labeling-related controls) where ISO 13485 is silent or less specific.

Practical implications for you (QSR → QMSR/ISO 13485 transition)

- **If you already have mature ISO 13485 certification:**
 - You’re structurally close—focus on **gap mapping** to QMSR’s added FDA-specific clauses (definitions, records, combination product clarifications, inspection expectations).
- **If you were historically “QSR-only”:**
 - You’ll need a **formal ISO 13485–aligned QMS architecture**: clause-based procedures, MDF/technical file structure, and clearer risk-based controls.
- **For DMF and global submissions:**
 - Harmonized QMSR/ISO 13485 framework should make it easier to present a single, defensible QMS narrative to FDA, EU, and other authorities, with appendices showing how U.S.-specific expectations are met.

