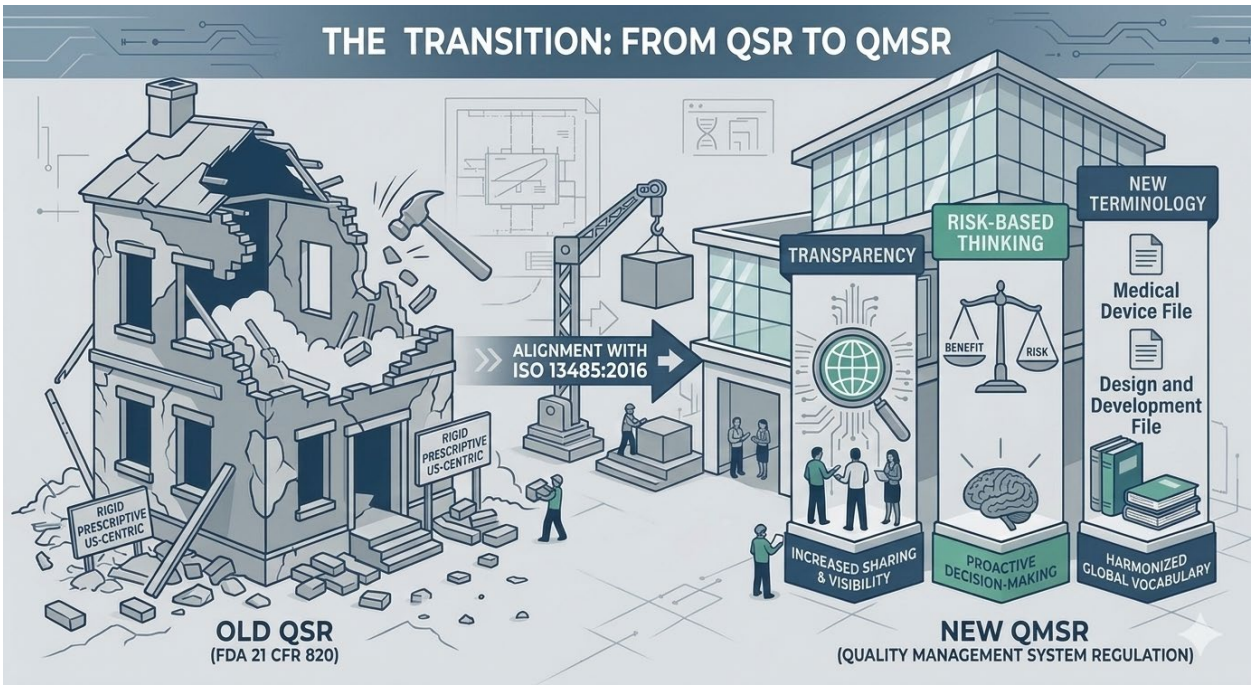

Transitioning from QSR to QMSR — The New Era of FDA Quality Oversight

On February 2, 2026, the U.S. Food and Drug Administration (FDA) officially retired the Quality System Regulation (QSR) in favor of the Quality Management System Regulation (QMSR). This transition represents the most significant overhaul of 21 CFR Part 820 in three decades. By incorporating the international standard ISO 13485:2016 by reference, FDA has moved to harmonize U.S. "Current Good Manufacturing Practices" (CGMP) with global regulations. For medical device manufacturers, this is more than a change in terminology; it is a fundamental shift in how the FDA evaluates quality, moving from a subsystem-based audit approach to a risk-centric, systemic evaluation.

Structural Harmonization and the "Medical Device File"

The most immediate change for manufacturers is the structural alignment of the Quality Management System (QMS). The previous QSR was organized into specific U.S.-centric subparts (A through O). The QMSR largely replaces this text with the clauses of ISO 13485:2016.

One of the most visible shifts is the "retirement" of legacy acronyms such as the Device Master Record (DMR), Design History File (DHF), and Device History Record (DHR). These have been consolidated into the ISO-aligned Medical Device File (MDF) and Design and

Development File. While the documentation requirements themselves remain largely unchanged, manufacturers should re-map their Quality Manuals to reflect the newly favored terminology. Failure to adopt this "global language" of quality is now viewed as a sign of an immature or outdated system and can be seen as red flag for inspectors to look harder for other potential issues during your next FDA inspection.

Risk Management Expectations

Under the old QSR, risk management was primarily explicitly required within Design Controls (21 CFR 820.30). Under the QMSR, the FDA now expects risk-based thinking to be integrated throughout the entire lifecycle of the device and every facet of the QMS. You and your company may have been doing this already. And that is good. However, this means that during an inspection, an investigator will look for evidence that risk assessments (aligned with ISO 14971) are used to inform decisions in:

- Purchasing and Supplier Controls: How the "criticality" of a component dictates the level of supplier oversight.
- Corrective and Preventive Action (CAPA): How the severity of a non-conformity determines the depth of the investigation.
- Software Validation: Using a risk-based approach to determine the extent of validation required for automated production processes.

The FDA's new inspectional playbook emphasizes that risk management is no longer a standalone document, but the "connective tissue" that justifies a company's operational decisions.

The End of Inspectional "Safe Harbors"

Perhaps the most jarring change for industry veterans is the elimination of the 820.180(c) exemption. Under the previous QSR, FDA investigators did not have the authority to request a company's internal quality audit reports, management review minutes, and supplier audit reports. This was intended to encourage candid internal self-reflection.

As of February 2026, these records are no longer exempt. The FDA's rationale is that since these documents are already reviewable by Notified Bodies and under the Medical Device Single Audit Program (MDSAP), the FDA should have equal access. This requires a shift in how these meetings are documented; minutes must be professional, action-oriented, and

capable of withstanding direct regulatory scrutiny without losing their effectiveness as a management tool.

Conclusion

The shift to QMSR is a double-edged sword for medical device manufacturers. On one hand, global companies benefit from a harmonized standard that reduces the burden of maintaining disparate systems for different markets. On the other hand, the FDA has increased the transparency requirements and deepened its focus on risk-based decision-making. Success in this new regulatory environment requires more than a "gap analysis" of paperwork; it requires a cultural shift where risk management and management responsibility are demonstrated through every record in the Medical Device File. Compliance is no longer about following a checklist—it is about proving a "state of control" through a globally recognized framework.

It is imperative that your management team review the new QMSR and then review your company's Quality Management System sooner rather than later. Bring in experts to help you align your Quality Management System with the new Regulations. Then continue the ongoing daily work to build a culture of compliance and quality with an emphasis on risk-based thinking and decision making in all aspects of your business. Your next FDA inspection will depend on it.