

Beyond the Clause Map: What the Quality Management System Regulation Actually Changed



A cGMP Consulting White Paper on the QMSR, Retained FDA Provisions, Record Access, and the New Inspection Model – October 1, 2026

Medical Devices | Combination Products | Quality Systems | QMSR

An educational resource for executive and technical leaders in FDA-regulated life sciences.

Executive Summary

On February 2, 2026, the Quality Management System Regulation took effect, replacing the Quality System Regulation that had governed device manufacturing since 1996. The revised 21 CFR Part 820 incorporates ISO 13485:2016 by reference, keeps a small set of FDA-specific provisions where the agency decided the standard did not fully cover United States requirements, and adopts the terminology of ISO 9000:2015 Clause 3. This is the most significant structural change to device quality regulation in three decades.

A lot of organizations treated the transition as a mapping exercise: find the ISO clause that corresponds to each former Part 820 subpart, update the procedural references, declare victory. That approach produces a tidy transition binder and an uncomfortable first inspection. The substantive changes are somewhere else, in the process-oriented, risk-based orientation ISO 13485 brings, in the FDA-specific requirements the agency retained precisely because the standard did not cover them, and in a change to record access that many transition plans skipped entirely.

That record access change deserves particular attention. The former Part 820 included an exception at 21 CFR 820.180(c) that shielded management review, internal quality audit, and supplier audit reports from routine FDA inspection. The QMSR does not maintain it. An organization's own assessment of its quality system, including the weaknesses it found and how it responded, is now subject to inspection. On top of that, the agency retired the Quality System Inspection Technique on the effective date and moved to an updated compliance program, so how inspections are conducted changed along with what they may examine.

This paper works through what the QMSR actually changed, where the FDA-specific provisions sit and why, how the new inspection model differs, and what the record access change means in practice. It lays out the transition work a clause map does not address, gives you a maturity assessment and implementation roadmap, and covers the extra complexity facing combination product manufacturers. Treat the QMSR as an operational realignment rather than a documentation update and the transition delivers the harmonization benefit it was designed to provide.

Introduction

For nearly thirty years, device manufacturers selling into both the United States and international markets ran two parallel quality frameworks. The domestic Quality System Regulation in 21 CFR Part 820 set out requirements directly in regulation. ISO 13485 set them out internationally, recognized by regulators in Europe, Canada, and elsewhere. The two were substantively similar, having shaped each other over decades, but they differed in structure, terminology, and detail. Global manufacturers ate the cost of maintaining a compliance overlay that added burden without adding quality.

The QMSR resolves that duplication. By incorporating ISO 13485:2016 by reference, the FDA made the international standard the baseline for United States device quality requirements, keeping supplemental provisions only where it decided the standard left gaps against United States statutory obligations. For organizations already running a mature ISO 13485 system, the transition is genuinely lighter than it would have been under a brand-new domestic framework. For organizations built around the legacy Part 820 structure, it is a substantial realignment.

The risk in either case is underestimating the work. Because the FDA described the requirements of the QSR and the QMSR as substantially similar, some organizations concluded that little would change in practice. That conclusion is defensible at the level of individual requirements and misleading at the level of the system. ISO 13485 organizes quality around processes and risk in a way the legacy Part 820 did not, the retained FDA provisions are retained precisely because they add something, and the inspection model and record access have both changed.

This paper is for the quality, regulatory, and operations leaders responsible for the transition and for the executives accountable for its outcome. It focuses on what changed in substance and on the work a clause-mapping exercise leaves undone.

Industry Background

The regulatory lineage matters for understanding what the QMSR does. The FDA codified current good manufacturing practice requirements for medical devices in 21 CFR Part 820 in 1978, and substantially revised it in 1996 to add design controls and align more closely with emerging international thinking. That 1996 Quality System Regulation governed device manufacturing for the next three decades.

ISO 13485 developed in parallel as the international consensus standard for medical device quality management systems, with the 2016 revision being the current edition. The FDA participated actively in its development, which is why the two frameworks converged substantively even while staying formally distinct. Regulators including Health Canada and European notified bodies relied on ISO 13485, and the Medical Device Single Audit Program built a multi-jurisdiction audit model on it. Keeping a separate United States framework got harder and harder to justify.

The FDA published the final rule, Medical Devices; Quality System Regulation Amendments, on February 2, 2024, setting an effective date two years later on February 2, 2026. The two-year interval was meant to let manufacturers plan and execute the transition. The rule amended the title of the regulation, incorporated ISO 13485:2016 and ISO 9000:2015 Clause 3 by reference, established additional requirements clarifying certain expectations, and made conforming edits to 21 CFR Part 4 addressing combination products. A later technical amendment updated references across other parts of Title 21 to reflect the new regulation, touching a large number of sections spread across many parts, which tells you how deeply the QSR was woven into the broader regulatory fabric.

The structural result is a much shorter Part 820. Where the QSR set out requirements across subparts A through O, the QMSR marks as reserved the areas the FDA decided ISO 13485 covers adequately, directing users to the standard. What remains in Part 820 is the scope, the definitions, the requirements for a quality management system linking to ISO clauses and FDA-specific obligations, the control of records provisions, and the device labeling and packaging controls. Each retained section exists for a reason, and those reasons are exactly where transition attention belongs.

Regulatory Landscape

Understanding the QMSR means knowing what was incorporated, what was retained, what was added, and what changed about inspection.

The Structure of the Revised Part 820

Section 820.1 establishes scope and applicability. Section 820.3 addresses definitions, adopting those in ISO 13485:2016 and ISO 9000:2015 Clause 3 while keeping certain FDA definitions that supersede the standards where conflicts exist, and adding terms defined in neither standard, including component. Section 820.7 sets out the incorporation by reference. Section 820.10 establishes the requirements for a quality management system, linking to ISO 13485 clauses while maintaining FDA-specific requirements including those related to medical device reporting, unique device identification, corrections and removals, tracking, and the applicability of design and development activities. Sections marked reserved direct users to ISO 13485 without additional requirements.

The FDA-Specific Provisions

Two retained sections warrant particular attention, because they exist where the FDA decided ISO 13485 was insufficient. Section 820.35, Control of Records, establishes requirements beyond ISO 13485 Clause 4.2.5, addressing information required under 21 CFR Part 803 related to complaint and servicing activities, documentation required to meet unique device identification requirements under 21 CFR Part 830, and the confidentiality of records sent to and received by the FDA. This section is more detailed and explicit about complaint and service record content than the legacy QSR was, and it repays careful reading. Section 820.45, Device Labeling and Packaging Controls, was retained because the FDA concluded ISO 13485 did not adequately address labeling inspection activities, and it preserves requirements for inspecting label accuracy prior to release.

The Record Access Change

The legacy Part 820 contained an exception at 21 CFR 820.180(c) that limited FDA access to management review, internal quality audit, and supplier audit reports during routine inspection. The QMSR does not maintain it. In the preamble to the final rule, the agency reasoned that because manufacturers already provide such documents to other regulators, making them available to FDA investigators imposes no additional burden. The practical consequence is significant: an organization's own critical assessment of its quality system, including the deficiencies it identified and how it responded, is now inspectable. Organizations used to candid internal audits protected from regulatory view have to reckon with the fact that those records are now visible, which raises the importance of actually addressing the deficiencies they identify.

The New Inspection Model

On February 2, 2026, the FDA stopped using the Quality System Inspection Technique for device inspections and began using the process described in the updated Inspection of Medical Device Manufacturers Compliance Program 7382.850. The agency also retired Inspection of Medical Device Manufacturers 7382.845 and Medical Device PMA Preapproval and PMA Postmarket Inspections 7383.001. It has indicated there will be no direct successor document functioning as a replacement QSIT. Inspectional authority is unchanged, and investigators may review records that are part of the quality management system including those created before the effective date, for which a comparative analysis demonstrating that earlier records meet QMSR requirements may be useful.

Combination Products and Related Frameworks

The final rule made conforming edits to 21 CFR Part 4 to clarify device quality management system requirements for combination products, though these edits do not change the current good manufacturing practice requirements for combination products themselves. Manufacturers operating under Part 4 therefore have to reconcile the QMSR-based device requirements with the drug current good manufacturing practice requirements that continue to apply. And the finalized Computer Software Assurance guidance was updated on February 3, 2026, one day after the QMSR effective date, specifically to align with the QMSR and ISO 13485:2016, which links software assurance practice to the new quality framework.

The FDA characterized the QSR and QMSR requirements as substantially similar, and at the level of individual requirements that is accurate. At the level of the system it is misleading. ISO 13485 organizes quality around processes and risk, the retained FDA sections exist because the standard left gaps, the inspection model has changed, and internal audit and management review records are now inspectable.

Current Industry Challenges

The transition challenges facing device organizations depend a lot on their starting point, but several are common to everyone.

Treating Transition as Terminology Substitution

The most common failure mode is approaching the QMSR as a find-and-replace exercise. Teams map former Part 820 subparts to ISO clauses, update procedural references, revise the quality manual, and call it done. That handles the vocabulary while leaving the underlying system organized exactly as it was. Because ISO 13485 takes a process-oriented, risk-based approach the legacy Part 820 did not, a system that merely renames its elements has not adopted the framework it now claims to follow, and the gap shows up the moment an investigator examines how processes interact rather than whether procedures exist.

Missing the Retained FDA Provisions

Organizations focused on the ISO clauses sometimes give too little attention to what remains in Part 820. Section 820.35 imposes record content requirements for complaints and servicing that are more explicit than the legacy QSR, and Section 820.45 preserves labeling controls the FDA found ISO 13485 inadequate to address. An organization that transitions to a well-implemented ISO 13485 system and assumes it has thereby satisfied Part 820 has missed precisely the provisions the agency retained because the standard did not cover them.

Underestimating the Record Access Change

A lot of transition plans never addressed the removal of the 820.180(c) exception. Organizations whose internal audits were candid because they were protected now have to reckon with those records being inspectable. The correct response is not to make internal audits less candid, which would degrade the very control that detects problems, but to make sure findings are addressed rigorously, so the record shows an organization that finds its own problems and fixes them. Organizations that do not adjust may find their internal audit records telling an investigator about deficiencies the organization never resolved.

Uncertainty About the Inspection Model

Retiring QSIT without a direct replacement document created uncertainty. Organizations that structured inspection readiness around the QSIT subsystem model have to adapt to an inspection approach described in an updated compliance program rather than in the familiar framework. Inspectional authority and the general character of quality system inspection are unchanged, but preparation built specifically around QSIT structure needs revisiting.

Historical Records and the Transition Boundary

Investigators may review records created before the effective date to assess QMSR compliance, which leaves organizations with a question about records generated under a differently structured system. The agency has noted that a comparative analysis demonstrating pre-transition documents and records meet QMSR requirements may be useful. Organizations that have not done this analysis may struggle to explain how records created under one framework demonstrate compliance with another.

Combination Product Complexity

Manufacturers of combination products have to operate under Part 4, reconciling device quality management system requirements now expressed through ISO 13485 with drug current good manufacturing practice requirements that continue in their existing form. The conforming edits clarified the device requirements without changing the drug requirements, leaving organizations to integrate two frameworks that are now differently structured. That is meaningful additional complexity a transition plan built around device requirements alone does not touch.

Risks of Poor Implementation

An incomplete transition creates exposure that surfaces at the first inspection under the new framework, when the cost of discovering the gap is highest.

Risk Category	Potential Consequence
Inspection findings	Observations arising from a system that adopted ISO terminology without adopting its process-oriented, risk-based structure, or that overlooked the retained FDA provisions in Sections 820.35 and 820.45.
Exposed internal records	Internal audit, management review, and supplier audit reports now inspectable, revealing identified deficiencies the organization did not adequately address.
Historical record gaps	Inability to demonstrate that records created before the effective date satisfy QMSR requirements, complicating inspection of any period spanning the transition.
Combination product exposure	Failure to reconcile QMSR-based device requirements with the drug CGMP requirements that continue to apply under Part 4.
Forfeited harmonization benefit	Continued maintenance of parallel compliance overlays, sustaining the duplication the QMSR was designed to eliminate.
Inspection readiness mismatch	Preparation built around the retired QSIT model rather than the current compliance program approach.

The record access change carries a distinctive risk profile, because it operates retrospectively on organizational behavior. An internal audit conducted in good faith years ago, identifying a deficiency that was documented and then insufficiently addressed, becomes a record an investigator may now read. You cannot revise history, but you can make sure open findings are closed rigorously and that the current record shows an organization that acts on what it finds. The alternative is an investigator learning about your known weaknesses from your own files.

There is also an opportunity cost to a superficial transition. The QMSR was designed to eliminate the burden of maintaining parallel frameworks, and organizations that integrate genuinely can reduce duplication, simplify audits across jurisdictions, and streamline their quality operations. Those that layer QMSR language over an unchanged legacy system keep the burden and collect none of the benefit, having paid the transition cost without taking the return.

Best Practices

A sound transition addresses the substance of the change: the process-oriented framework, the retained FDA provisions, the record access change, and the new inspection model.

Build a Genuine Crosswalk, Then Go Past It

A clause-level crosswalk between the legacy QSR, ISO 13485:2016, and the retained Part 820 provisions is necessary but not sufficient. The crosswalk establishes coverage. The transition work is confirming that the underlying processes actually operate as ISO 13485 contemplates, with defined process interactions, risk-based thinking applied throughout, and the process approach reflected in how the system is managed rather than only in how it is documented. Test whether your system would be recognizable as an ISO 13485 system to someone who read only its operations, not its manual.

Give the Retained Provisions Explicit Attention

Sections 820.35 and 820.45 exist because the FDA decided ISO 13485 did not adequately cover their subject matter. Read these sections carefully and verify compliance directly rather than assuming ISO conformity suffices. Section 820.35 warrants particular scrutiny for its explicit content requirements for complaint and service records, including when complaints must be investigated, and for its treatment of unique device identification documentation and record confidentiality. Section 820.45 requires attention to label accuracy inspection before release.

Prepare for Inspectable Internal Records

Review open internal audit findings, management review actions, and supplier audit results with the awareness that these records are now inspectable, and make sure identified deficiencies have been addressed with evidence of effectiveness. The correct posture is a candid internal audit function whose findings are rigorously closed, producing a record that demonstrates a self-correcting organization. Resist any impulse to soften internal audits, which would remove the control that finds problems while doing nothing about the problems themselves.

Realign Inspection Readiness

Readiness built around the QSIT subsystem model should be revisited in light of the updated compliance program. Make sure the records the new inspection approach may examine, including management review, internal audit, supplier audit, complaint investigations, and risk evaluations, are organized, current, and retrievable. Records organization and retrieval deserve as much attention as procedure wording, because an inspection tests whether you can produce what you claim to maintain.

Address the Historical Record Boundary

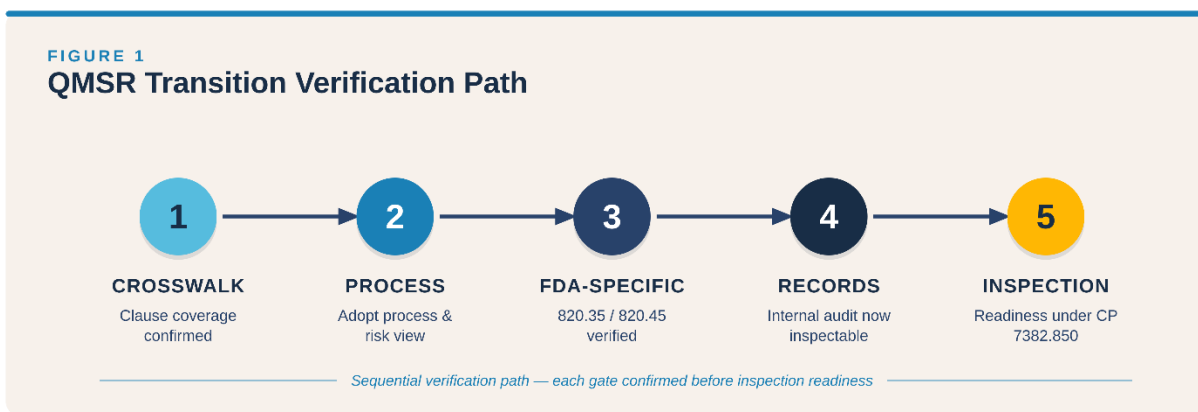
Because investigators may review records created before the effective date, perform and document a comparative analysis demonstrating that pre-transition records satisfy QMSR requirements. That analysis converts a potential inspection difficulty into a prepared answer, and it is a great deal easier to construct deliberately than to improvise during an inspection.

Integrate Combination Products and Software Assurance

Combination product manufacturers should explicitly reconcile the QMSR-based device requirements with the drug current good manufacturing practice requirements that continue to apply under Part 4, documenting how the integrated system satisfies both. Align your software assurance practice with the Computer Software Assurance guidance updated in February 2026 specifically to align with the QMSR and ISO 13485:2016, so computerized systems supporting the quality system are assured within the same risk-based framework the QMSR embodies.

Implementation Roadmap

The roadmap below suits organizations completing or remediating a transition, and those verifying that a completed transition addressed the substance.



Step 1: Assess the Current State

Determine honestly whether the transition changed the system or only its vocabulary. Examine whether processes and their interactions are defined, whether risk-based thinking operates throughout, and whether the retained FDA provisions were addressed directly. Organizations that completed a transition should treat this as verification rather than assuming completion.

Step 2: Perform a Gap Assessment

Assess the quality management system against ISO 13485:2016 clause by clause and against the retained Part 820 provisions separately, since ISO conformity does not establish compliance with the sections the FDA retained because the standard was insufficient. Include the record access change and the inspection model in the assessment scope.

Step 3: Develop the Remediation Strategy

Prioritize gaps by inspection exposure and by their effect on the system's actual functioning. Distinguish documentation gaps from process gaps, since the latter require operational change rather than revised text. Establish ownership and timelines.

Step 4: Update Procedures and Align Processes

Revise procedures to reflect ISO 13485 structure and the retained Part 820 requirements, and, more importantly, align the underlying processes with the process-oriented and risk-based approach the standard contemplates. Confirm that Sections 820.35 and 820.45 requirements are addressed explicitly rather than assumed.

Step 5: Address the Records Position

Review open internal audit and management review findings and close them with evidence of effectiveness. Perform and document the comparative analysis addressing pre-transition records. Organize records for retrieval under the new inspection approach.

Step 6: Train Personnel

Train quality, regulatory, engineering, and leadership teams on the QMSR structure, the ISO 13485 process approach, the retained FDA requirements, the record access change, and the updated inspection model. Leadership training matters here because management review is now inspectable and its quality reflects on the organization.

Step 7: Verify Through Internal Audit

Audit the transitioned system against the QMSR and ISO 13485, using the audit to test whether the system operates as claimed rather than whether documents exist. Treat findings as the chance to correct before an investigator does, recognizing that the audit record itself is now inspectable.

Step 8: Sustain and Improve

Establish ongoing management review that satisfies both ISO 13485 expectations and the reality of inspectability, and use the harmonized framework to reduce duplication across jurisdictions. The transition's return comes from operating a single coherent system rather than maintaining parallel overlays.

Technology Considerations

Technology considerations for the QMSR transition center on records, process management, and the alignment of software assurance with the new framework.

Electronic quality management systems structure the processes ISO 13485 contemplates and hold the records the QMSR requires. The record access change raises the practical importance of records organization and retrieval, since management review, internal audit, and supplier audit reports must now be producible for inspection. Systems that maintain these records with clear linkage between findings and

their resolution let an organization demonstrate that it acts on what it finds, which is the story those records should tell.

The alignment between the QMSR and the Computer Software Assurance guidance is deliberate and operationally significant. The guidance was updated on February 3, 2026, specifically to align with the QMSR and ISO 13485:2016, which means software used in production or the quality system should be assured within a risk-based framework consistent with the quality system that governs it. Organizations transitioning to the QMSR should align their software assurance practice at the same time rather than treating the two as separate initiatives, since the regulatory framework now treats them as connected.

For combination product manufacturers, systems have to accommodate two frameworks that are now differently structured, maintaining device records under an ISO 13485-based system while satisfying drug current good manufacturing practice record requirements that continue in their existing form. Configuration that forces one framework onto the other typically satisfies neither, and the integration deserves deliberate design rather than a default.

Future Outlook

The QMSR advances a broader trajectory toward international regulatory convergence. With the United States now relying on ISO 13485:2016 as the baseline for device quality requirements, the major regulatory frameworks are more aligned than at any previous point, which should reduce the burden on global manufacturers and support programs such as the Medical Device Single Audit Program. Organizations that integrate genuinely will realize this benefit; those maintaining parallel overlays will not.

The inspection model will keep developing. With QSIT retired and no direct successor document, the practical character of quality system inspection under the updated compliance program will get clearer as experience accumulates. Expect inspection to remain rigorous and the expanded record access to shape what investigators examine, with management review and internal audit records offering a direct view into the organization's self-assessment.

The alignment between the QMSR and risk-based software assurance points toward the future direction. As artificial intelligence, cloud systems, and connected devices become more central to device manufacturing and to devices themselves, quality systems will need to govern technology the 1996 framework never contemplated. The process-oriented, risk-based structure the QMSR adopts is better suited to that than the framework it replaced, which is part of the modernization the change was intended to deliver. Organizations that adopt the framework in substance will be better positioned for what follows than those that adopted only its vocabulary.

How cGMP Consulting Can Help

The QMSR transition rewards organizations that address its substance and exposes those that addressed only its terminology. cGMP Consulting works with device and combination product manufacturers to verify, complete, or remediate the transition and to prepare for inspection under the new model.

Our consultants perform gap assessments against ISO 13485:2016 and against the retained Part 820 provisions separately, testing whether the system operates as a process-oriented, risk-based framework rather than a renamed legacy system. We help organizations address Sections 820.35 and 820.45 explicitly, prepare for the inspectability of management review and internal audit records, and construct the comparative analysis addressing pre-transition records. We support inspection readiness aligned to the updated compliance program rather than the retired QSIT model, and we help combination product manufacturers reconcile QMSR device requirements with the drug current good manufacturing practice requirements that continue under Part 4. And because the Computer Software Assurance guidance was aligned to the QMSR, we help organizations integrate software assurance into the transitioned quality system rather than treating it separately.

Our approach is consultative and grounded in how quality systems are actually examined during inspection. We aim to leave organizations with a single coherent system that delivers the harmonization benefit the QMSR was designed to provide.

Conclusion

The Quality Management System Regulation took effect on February 2, 2026, making ISO 13485:2016 the baseline for United States device quality requirements and ending three decades of a separate domestic framework. The FDA characterized the requirements as substantially similar to those they replaced, and at the level of individual requirements that characterization holds. At the level of the system, it conceals the work.

The substance of the change lies in the process-oriented, risk-based orientation ISO 13485 brings, in the FDA-specific provisions retained at Sections 820.35 and 820.45 precisely because the standard did not cover them, in the removal of the exception that protected management review and internal audit records from routine inspection, and in the retirement of QSIT in favor of an updated compliance program. A transition that mapped clauses and updated procedural references has addressed none of these.

Organizations that complete the transition in substance will find that it delivers what it promised: a single coherent quality system, aligned with the frameworks other regulators use, without the parallel overlay global manufacturers carried for decades. Those that treated it as a find-and-replace exercise will discover the gap at their first inspection under the new model, when the cost of discovery is highest and the record of their own internal audits is sitting in front of the investigator asking the questions.

If your organization is completing, verifying, or remediating its QMSR transition, or preparing for inspection under the updated compliance program, the experienced consultants at cGMP Consulting can help assess your current state, identify gaps, and develop practical solutions tailored to your business objectives. To start a confidential conversation, complete the Contact Us form at cgmpconsulting.com/contact-us.

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