

FDA QMSR & ISO 13485: New Inspection Playbook Guide

By Adrien Laurent, CEO at IntuitionLabs • 2/27/2026 • 35 min read

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QMSR Is Live: What Device Manufacturers Need to Know About the New FDA Inspection Playbook

Executive Summary: In February 2026 the FDA's new **Quality Management System Regulation (QMSR)** became effective, fundamentally overhauling the long-standing 21 CFR Part 820 (the Quality System Regulation, QSR) for medical devices. The QMSR formally *incorporates ISO 13485:2016* by reference and shifts U.S. device inspections to a risk-based model. For device manufacturers, this means two years of transition (the final rule was published Feb. 2, 2024 with compliance required by Feb. 2, 2026 (^[1] www.fda.gov) (^[2] www.thefdagroup.com)) have now ended – companies must now operate under the ISO-aligned QMSR and be prepared for the FDA's new *inspection "playbook"* (Compliance Program Manual 7382.850). Key takeaways include: (1) **ISO Alignment:** The new rule mandates ISO 13485:2016 as the framework for device quality systems (^[1] www.fda.gov) (^[2] www.thefdagroup.com), including explicit risk management throughout design, production, and post-market activities. (2) **Inspection Changes:** The old QSIT subsystems (CAPA, Production, Design, Management) have been replaced by **six QMS Areas** (Management Oversight; Design & Development; Production & Service Provision; Outsourcing & Purchasing; Change Control; Measurement, Analysis & Improvement) plus **four Other Applicable FDA Requirements (OAFRs)** (Medical Device Reporting, Corrections & Removals, Tracking, UDI) (^[3] www.thefdagroup.com) (^[4] www.thefdagroup.com). FDA inspections are now risk-driven, with inspectors using the firm's risk management documentation to guide what to examine (^[5] www.thefdagroup.com). (3) **Inspection Models:** FDA defines *two inspection models* under QMSR: a **baseline/preapproval model** with prescriptive element checks, and a **non-baseline/for-cause model** where inspectors pick at least one element from each QMS Area based on product risk (^[6] www.thefdagroup.com) (see **Table 1**). (4) **Preparation Required:** Manufacturers must ensure their QMS is fully compliant with ISO 13485 – including clauses on risk management, supplier control, information security, and process validation – and should practice documenting and demonstrating those processes, as inspectors will request records such as internal and supplier audit reports and management review minutes (^[7] www.thefdagroup.com) (^[8] www.thefdagroup.com). The FDA has explicitly shifted to examining audit and review documentation that were once considered internal formalities (^[7] www.thefdagroup.com) (^[8] www.thefdagroup.com). (5) **Regulatory Refresh:** The FDA has retired several old documents (QM Inspection Technique, PMA inspection manuals) and published the new CP 7382.850 (78 pages) as the "how-to" for inspections (^[9] www.fda.gov) (^[10] www.thefdagroup.com). This CP is unusually detailed – experts urge firms to read it carefully, as it **"tells you exactly how FDA plans to inspect"** (^[11] www.thefdagroup.com). Finally, device makers should be aware that even companies with ISO certification are not exempt; the FDA emphasizes that an ISO 13485 certificate "does not substitute" for complying with QMSR (^[12] www.thefdagroup.com).

This report provides a comprehensive analysis of the QMSR rule, the new FDA inspection framework, and the implications for manufacturers. It covers historical context of the Quality System Regulation, details of the QMSR final rule and requirements, the updated inspection process, practical guidance for compliance, and expert commentary or case perspectives. Extensive authoritative sources and FDA guidance documents are cited throughout.

Introduction and Background

The U.S. **Quality System Regulation (QSR)** for medical devices – codified at 21 CFR Part 820 – was originally established by FDA in 1978 (effective December 18, 1978) under Section 520(f) of the FD&C Act (^[13] www.fda.gov). QSR was substantially revised in the mid-1990s (a 1996 final rule, effective June 1, 1997 (^[14] www.fda.gov)) to add design controls and to align as much as possible with then-current international standards

(ISO 9001 and draft ISO 13485). Aside from these updates, the substance of 21 CFR 820 remained largely unchanged for decades. Meanwhile, the global medical device industry continued to move toward the ISO 13485 standard as the recognized framework for device quality management.

In the 2010s and early 2020s, the regulatory landscape shifted further toward risk-based and lifecycle approaches. The FDA itself had incentivized a **risk-based inspection schedule** via the FDA Reauthorization Act of 2017 (FDARA) (^[15] www.thefdagroup.com). Congress additionally emphasized total product lifecycle oversight in the Food and Drug Omnibus Reform Act (FDORA) of 2022 (^[16] www.thefdagroup.com). Industry experts also increasingly pointed out that the existing QSR was outdated – for example, it mentioned “risk” only once and had no provisions for emerging concerns such as cybersecurity, usability engineering, or formal post-market surveillance (^[17] medicaldeviceacademy.com) (^[18] medicaldeviceacademy.com). In this context, FDA began development of a new Quality Management System Regulation (QMSR) to harmonize U.S. device CGMPs with international standards.

On **February 23, 2022**, FDA published a *proposed* rule to amend 21 CFR 820, justifying it on grounds of redundancy and encouraging harmonization between U.S. CGMP and ISO 13485 (among other arguments) (^[19] medicaldeviceacademy.com). Although FDA initially considered a 12-month implementation period, the agency and commenters quickly recognized that a multi-year transition was more realistic. After extensive notice-and-comment (including comments urging more transition time), the FDA issued the **final QMSR rule on February 2, 2024 (89 FR 7496)** (^[2] www.thefdagroup.com). Critically, FDA allowed a two-year transition period: the final rule is *effective* February 2, 2026 (^[1] www.fda.gov). As of that date, device manufacturers must have updated their quality systems to meet the new requirements; FDA has retired the old QSR and adopted the new QMSR framework.

The QMSR final rule **renames** Part 820 as the “Quality Management System Regulation” and incorporates ISO 13485:2016 by reference (^[20] www.fda.gov). In practical terms, this means that as of Feb 2, 2026, 21 CFR 820 behaves as if it were largely ISO 13485, subject to U.S. law. The FDA emphasizes that the move “*harmonizes the FDA’s CGMP framework with that used by other regulatory authorities*” (^[21] www.fda.gov), reflecting global convergence. FDA also notes that the QMSR specifically “*requires risk management*,” a concept embedded throughout ISO 13485 but only implicit in the old QSR (^[20] www.fda.gov). In short, device quality systems in the U.S. now officially must comply with the processes, documentation, and risk-based philosophy of ISO 13485.

Given this background, device manufacturers should prepare for two major changes: (1) **What the law requires** (i.e. the substantive QMSR requirements) and (2) **How FDA will inspect** under the new framework. The sections below analyze each in depth, with citations to official FDA sources, regulatory analyses, and expert commentary.

The QMSR Final Rule: Key Provisions and Requirements

Incorporation of ISO 13485:2016

The centerpiece of the QMSR rule is that 21 CFR 820 is amended to *incorporate ISO 13485:2016 by reference* (^[1] www.fda.gov) (^[20] www.fda.gov). In practice, FDA has adopted ISO 13485 (the globally recognized standard for medical device QMS) as the baseline quality system template for U.S. device firms. The QMSR page on FDA’s website explicitly states:

“The Quality Management System Regulation (QMSR) that became effective on February 2, 2026, amends the device CGMP requirements of 21 CFR Part 820, incorporating by reference the international standard specific for medical device quality management systems... ISO 13485:2016... This action harmonizes the FDA’s CGMP regulatory framework with that used by other regulatory authorities.” (^[1] www.fda.gov)

To facilitate a smooth transition, FDA also incorporated **Clause 3 of ISO 9000:2015** (quality management fundamentals and vocabulary) by reference (^[20] www.fda.gov), allowing U.S. regulations to use ISO terms. Crucially, the rule provides that to the **extent any ISO clause conflicts with U.S. law**, U.S. law prevails (^[22] www.fda.gov). In other words, companies must meet ISO 13485:2016 requirements *and* still comply with statutory mandates (e.g. complaint handling under the FD&C Act).

For manufacturers, this means that **the specific provisions of ISO 13485:2016 are now effectively incorporated into U.S. law**. Any quality system requirements in ISO 13485 that were previously not in 21 CFR 820 must now be implemented. FDA spelled this out by mapping certain QMSR requirements to ISO clauses. For example:

- **Risk Management:** ISO 13485 has a dedicated clause on documenting risk management plans, evaluating risk, and controlling risk (closely linked with ISO 14971). The QMSR explicitly *“requires risk management”* (^[20] www.fda.gov) by making ISO 13485 the baseline. (In contrast, the old QSR only mentioned risk once, in design planning (^[17] medicaldeviceacademy.com)). Under QMSR, firms must integrate risk analysis and risk-control measures throughout design, supplier selection, production, and post-market.
- **Quality Manual:** Unlike the old QSR, ISO 13485 requires a **Quality Manual** that describes the QMS and references procedures (ISO 13485 Clause 4.2.2). FDA’s QMSR now includes this: e.g. in the “Management Oversight” area, elements include the *Quality Manual* and the *Medical Device File* (^[23] www.thefdagroup.com). Thus, manufacturers must establish a formal quality manual if they have not already.
- **Supplier/Outsourcing Controls:** ISO 13485 has extensive clauses on purchasing and supplier controls (Clause 7.4) as well as outsourcing processes (Clause 4.1.5). The new QMSR dedicates an entire QMS Area to **Outsourcing and Purchasing**, covering the purchasing process, supplier evaluations, and monitoring** (^[24] www.thefdagroup.com). By contrast, the old 21 CFR 820 had a narrower “Purchasing Controls” section (§820.50) with limited detail. Now, FDA explicitly expects firms to manage outsourced services and purchased products per the ISO clauses (for example, requiring defined purchasing information, supplier evaluation, etc.) (^[24] www.thefdagroup.com).
- **Production Controls and Process Validation:** ISO 13485’s approach to production and process control (Clause 7.5) is now the governing standard for device manufacturers. The QMSR merges the ISO approach in the **Production and Service Provision** area, which includes clauses on infrastructure, environmental control, sterility/process validation, traceability, and equipment calibration (^[25] www.thefdagroup.com). (These cover and extend the old QSR sections on process validation, production procedures, and equipment.)
- **Design & Development:** ISO 13485 Clause 7.3 covers the entire design and development lifecycle with emphasis on risk, verification, validation, design transfer, and design change control. The QMSR **Design and Development** area corresponds to this, including all phases from inputs/outputs to validation and transfer (^[26] www.thefdagroup.com). Notably, software validation (for any software that is part of the device or used in a controlled process) is explicitly required by ISO and thus by QMSR (^[27] medicaldeviceacademy.com). In contrast, 21 CFR 820.30 (design controls) did not explicitly cover aspects like “quality management software” validation or software lifecycle per se.
- **Internal Audits & Management Review:** One of the most consequential additions is that internal audits and management reviews (ISO 13485 Clause 8.2.2 and 5.6) are now explicitly subject to FDA scrutiny. Under the old QSR, these activities (820.22 and 820.20) were often formalities seldom examined in depth. Under QMSR, FDA can and will request internal audit records, supplier audits, and management review minutes (^[7] www.thefdagroup.com). In fact, the FDA Group commentary calls this “the single most consequential change” – urging companies to treat their audits and reviews as *auditable* records (^[8] www.thefdagroup.com). Manufacturers should ensure these processes are rigorous and well-documented, because investigators will look for evidence that management review actually influenced corrective actions and improvements.

- Other New Expectations:** The QMSR's incorporation of ISO 13485 also implicitly updates expectations for areas like cybersecurity and usability (human factors). For example, ISO 13485 (through its reference to IEC 62366-1) implies usability engineering and use-related risk analysis for devices, a topic largely absent in CFR 820 ^[18] medicaldeviceacademy.com. While QMSR does not independently mandate IEC 62366-1, the spirit of ISO 13485 means FDA will expect manufacturers to address these issues in their design risk processes. Similarly, ISO 13485 references ISO/TR 20416 on post-market surveillance; QMSR itself does not codify PMS reporting beyond existing CAPA/Complaint/MDR requirements, but the broad adoption of risk management suggests a more proactive stance on monitoring field data.
- CGMP Exemptions:** The FDA explicitly maintained existing exemptions. Devices that were CGMP-exempt under classification (21 CFR 862–892) remain exempt from most QMSR requirements ^[28] www.fda.gov. However, *exemption from Part 820 does not exempt* a manufacturer from recordkeeping of complaints or general quality records (such as complaint files) ^[29] www.fda.gov. Also, even an investigational (IDE) device manufacturer is *not* exempt from design and development requirements – IDE products must still meet design controls under QMSR and ISO 13485 Clause 7 ^[30] www.fda.gov. (This is a change: under earlier FDA guidance, it was sometimes unclear that IDE projects needed full design control compliance.)

Summary of QMSR Versus Old QSR Requirements

In sum, transitioning to QMSR means device manufacturers must implement anything ISO 13485:2016 requires, unless overridden by U.S. law. Table 2 (below) highlights some of the key differences between the old QSR framework (and its corresponding inspection approach) versus the new QMSR framework. It is not exhaustive, but illustrates the shift in emphasis:

Aspect	Under Old QSR (21 CFR 820)	Under New QMSR (ISO 13485-based)
Standard Reference	FDA's QSR (21 CFR 820) encompassing GMPs from 1978, plus 1996 revision.	ISO 13485:2016 (and ISO 9000 definitions) incorporated into Part 820 ^[1] www.fda.gov ^[20] www.fda.gov .
Risk Management	Risk mentioned only once (for design), no formal risk mgmt process.	Explicit requirement for risk management throughout QMS (ISO 13485, Clause 7.1) ^[20] www.fda.gov .
Quality Manual & Docs	Not explicitly required; firms could produce them voluntarily.	Formal Quality Manual required (ISO 13485 Clause 4.2.2); uses "Medical Device File" term ^[23] www.thefdagroup.com .
Supplier Controls	§820.50 (Purchasing Controls) required supplier evaluation, but limited scope.	Entire Outsourcing & Purchasing QMS area dedicated to supplier evaluation, verification, and monitoring (ISO 13485 Clauses 7.4, 7.1.5) ^[24] www.thefdagroup.com .
Design & Development	§820.30 required design controls (inputs, reviews, etc.) but less explicit on software/usability.	Comprehensive Design & Development area (ISO 13485 Clauses 7.3) covering full design lifecycle including software validation and human factors considerations ^[26] www.thefdagroup.com .
Process Validation	§820.75 requires process validation for special processes, sterilization, etc.	Part of Production & Service area (ISO 13485 Clauses 7.5) including validation of automated and sterile processes ^[25] www.thefdagroup.com .
Internal Audit & Mgmt Review	§820.22 audit & §820.20 review required but historically treated as formalities.	Now explicitly in inspection scope. FDA expects candor in audit reports; will review internal audits, supplier audits, and management review minutes ^[7] www.thefdagroup.com ^[8] www.thefdagroup.com .
Complaint Handling & CAPA	§820.198 (Complaint files) and §820.100 (CAPA) enforced as before.	These are included under Measurement, Analysis & Improvement area (ISO 13485 Clause 8.5) ^[31] www.thefdagroup.com . Emphasis remains on reactive corrections and preventive actions.

Aspect	Under Old QSR (21 CFR 820)	Under New QMSR (ISO 13485-based)
UDI, MDR, Tracking, Recall	UDIs (§820.30(f)), MDR (21 CFR 803), Device Tracking (21 CFR 821) etc., addressed in various regs.	Treated as Other Applicable FDA Requirements (OAFRs) – specifically enumerated and inspected (UDI, MDR, 806 Corrections, 821 Tracking) ([32] www.thefdagroup.com).
Global Harmonization	No formal alignment; many manufacturers also did ISO 13485 separately.	Formally aligned; FDA's CGMP now formally harmonized with global standard ([21] www.fda.gov), reducing duplicative audits.

Sources: FDA QMSR rule and guidance ([21] www.fda.gov) ([23] www.thefdagroup.com) ([7] www.thefdagroup.com), regulatory analyses ([17] medicaldeviceacademy.com) ([26] www.thefdagroup.com).

The New FDA Inspection Framework (CP 7382.850)

With the QMSR effective on Feb 2, 2026, FDA simultaneously overhauled its inspection process for device manufacturers. The legacy **Quality System Inspection Technique (QSIT)** – a subpart-based, checklist-oriented method used for decades – has been *retired*. As FDA announced, “On February 2, 2026, the FDA stopped using the Quality System Inspection Technique (QSIT) for device inspections”, and instead is employing the **Inspection of Medical Device Manufacturers (CP 7382.850)** ([9] www.fda.gov). This new Compliance Program manual (published Jan 30, 2026) is now the FDA's operating “playbook” for device inspections ([33] www.thefdagroup.com). It is unusually transparent: experts urge firms to read it, noting that “CP 7382.850 is an unusually transparent document. It tells you exactly how FDA plans to inspect, what investigators are instructed to look for, how they prioritize their coverage, and what triggers escalation.” ([11] www.thefdagroup.com).

The key feature of CP 7382.850 is its **risk-based, integrated inspection model**. Instead of four fixed subsystems (Management Controls, Design Controls, CAPA, Production/Process Controls) as in QSIT, the new program organizes inspections around **six QMS Areas** plus **four OAFRs** ([3] www.thefdagroup.com) ([4] www.thefdagroup.com) (see sections above). The **six QMS Areas** (Table 2) align with major ISO 13485 clauses:

- **Management Oversight:** Top management responsibilities, quality policy, quality manual, the *Medical Device File*, document control, and overall risk-based decision making ([23] www.thefdagroup.com).
- **Design and Development:** Full design life-cycle, including inputs, outputs, reviews, verification, validation, design transfer, and design change control ([26] www.thefdagroup.com).
- **Production and Service Provision:** Process controls that ensure safe devices, including environmental controls, contamination control, cleanliness, installation/servicing, process validation (including sterilization and software processes), traceability, and equipment calibration ([25] www.thefdagroup.com).
- **Outsourcing and Purchasing:** Controls over outsourced processes and purchased products – suppliers must be evaluated, and incoming product verified per ISO purchasing requirements ([24] www.thefdagroup.com).
- **Change Control:** Oversight of all changes – to products, processes, software, and even changes to the QMS itself – including risk evaluation before change implementation ([34] www.thefdagroup.com).
- **Measurement, Analysis, and Improvement (MA&I):** Includes customer feedback, complaint handling, internal audit, data analysis, control of nonconforming product, and CAPA ([31] www.thefdagroup.com). Essentially, MA&I covers the monitoring and corrective-action system.

The **four OAFRs** considered in every inspection are: Medical Device Reporting (21 CFR 803), Corrections and Removals reporting (21 CFR 806), Medical Device Tracking (21 CFR 821), and Unique Device Identification (21 CFR 830) ([4] www.thefdagroup.com). This means a reviewer must always check that adverse events are promptly reported, recalls/corrections are documented, tracking requirements are met for certain devices, and UDIs are

properly assigned and submitted. (In a final step, FDA consciously aligned **21 CFR Part 4** for combination products with the QMSR: any combination product inspection that involves a device component is now governed by these QMSR principles (^[35] www.thefdagroup.com).)

Inspection Philosophy and Process

Figure-wise, CP 7382.850 begins with an explicit mission diagram: **Patients and users are placed at the center, surrounded by a ring of “Management of Risk” modeled on ISO 13485’s emphasis, with the six QMS areas radiating outward and the OAFRs forming an outer hexagon** (^[36] www.thefdagroup.com). This symbolizes the new philosophy: FDA inspections hinge on risk. As one expert blog observed, the compliance program “places patients and users at the center” and “explicitly states that the goal of FDA inspections is... whether risk management and risk-based decision making are effectively used in the QMS.” (^[36] www.thefdagroup.com) (^[37] www.thefdagroup.com). Inspectors are instructed to use the manufacturer’s own risk management documentation to guide the inspection: if a product has identified risks, investigators will prioritize the QMS elements related to those risk areas (^[37] www.thefdagroup.com). The net effect is that FDA is *no longer simply ticking boxes to see if procedures exist; they’re “following risk signals through your quality system.”* (^[5] www.thefdagroup.com).

Practically, CP 7382.850 defines **two inspection models** depending on the type of inspection (e.g. baseline vs for-cause). **Model 2 (Baseline/Pre-Approval)**: applies when the manufacturer has never had a prior FDA inspection or MDSAP audit, or when doing a PMA preapproval inspection. In this model, FDA takes a wide, standardized approach: it requires review of a prescribed set of elements in each QMS Area. Investigators must inspect *at least 22 elements* of the 6 QMS Areas for non-sterile devices (23 elements if the device is sterile), plus all 4 OAFRs (^[38] www.thefdagroup.com). (For PMA preapproval, the OAFRs are excluded.) In other words, Model 2 is relatively prescriptive: a checklist of required topics.

Model 1 (Non-Baseline/Follow-up/For-Cause): applies to recurrence inspections, surveillance, compliance follow-up, “for-cause” inspections, specific product risk assignments, PMA postmarket inspections, etc (^[6] www.thefdagroup.com). Here, inspectors take a *risk-based* approach: at minimum, they must cover **one element from each of the six QMS Areas and all OAFRs**, but they get to choose which elements based on product risks (^[6] www.thefdagroup.com). For example, if a device has a known sterility risk, the investigator might delve deeply into the sterilization and contamination-control elements of the Production area; if a product is software-heavy, the Design & Development and Production software elements might get heightened focus. Under Model 1, there is *no fixed set of elements* beyond one per area; the CP explicitly allows investigators to expand the inspection scope if risks or findings warrant it (^[39] www.thefdagroup.com). In short, Model 1 is flexible and driven by risk signals, whereas Model 2 is a mandatory “open-book test” of broad QMS coverage.

These two models are summarized in **Table 1** below.

Inspection Model	Applicability	Inspection Scope
Model 2 (Baseline/Pre-Approval)	Baseline surveillance (no prior FDA inspection/MDSAP audit); PMA preapproval inspections.	FDA inspects a <i>prescribed set of elements</i> : at least 22 elements (non-sterile device) or 23 elements (sterile device) across the six QMS Areas, plus all four OAFRs (except OAFRs omitted for PMA-only inspections) (^[38] www.thefdagroup.com). This model is highly prescriptive.
Model 1 (Non-Baseline/For-Cause)	Non-baseline surveillance, follow-up, for-cause, SPRA, PMA postmarket.	FDA selects <i>at least one element from each of the six QMS Areas</i> and evaluates each of the four OAFRs (^[6] www.thefdagroup.com). The specific elements chosen are guided by identified product risks, and investigators may dive deeper into areas connected by risk or prior findings. (Inspectors also review registration/listing, previous 483s, and assignment instructions in all cases (^[40] www.thefdagroup.com).)

Table 1. Inspection models defined in FDA Compliance Program 7382.850. Inspections either follow Model 2 (baseline) or Model 1 (non-baseline), with different coverage requirements (^[6] www.thefdagroup.com) (^[40] www.thefdagroup.com).

Importantly, the new CP **eliminates QSIT’s fixed sampling tables**. Under the old QSIT, inspectors used stock tables to determine how many system records or how many production lots to review. In CP 7382.850, FDA provides *no such tables*. Instead, investigators are instructed to select records based on risk and professional judgment (^[41] www.thefdagroup.com). As one analysis notes, “the new compliance program contains no sampling tables... investigators select records based on identified product risks and their own professional judgment.” (^[41] www.thefdagroup.com). This grants FDA more flexibility (and introduces more unpredictability for firms), because the number of documents reviewed will depend on the scenario. In practice, companies should assume that multiple samples of each category (e.g. complaint records, CAPA files, validation protocols) may be examined if risk or findings indicate.

In terms of outcomes, the CP retains FDA’s familiar inspection classifications: **No Action Indicated (NAI)**, **Voluntary Action Indicated (VAI)**, or **Official Action Indicated (OAI)**, defined in the usual way (^[42] www.thefdagroup.com). The new program also codifies FDA’s “voluntary correction” preference: manufacturers have 15 business days after the inspection closes to submit written corrective action plans detailing how they will address observed deficiencies (^[43] www.thefdagroup.com). FDA still ultimately can take enforcement, but it encourages prompt voluntary correction as the first step to protect public health (^[43] www.thefdagroup.com) (^[44] www.thefdagroup.com).

Comparing Old QSIT versus New QMSR Inspections

Table 2 below contrasts several high-level inspection features under the legacy QSIT approach with the new QMSR-based approach. Many of these points have been highlighted by industry analysts:

Feature	QSIT (Pre-2026)	QMSR (2026 onward)
Inspection Philosophy	Subsystem/checklist-focused: Inspect Management Controls, Design, CAPA, Prod/Process separately; emphasis on presence of procedures.	Risk-driven, integrated process: Focus on ensuring patient safety and product risk are addressed across the QMS (^[45] www.thefdagroup.com) (^[37] www.thefdagroup.com) (centered on risk management, not just checking paperwork).
Organization	4 main subsystems (Management, Design, CAPA, Prod/Proc) plus miscellaneous (Purchasing, Records, Servicing).	6 QMS Areas (as listed above) plus 4 OAFRs (MDR, 806, 821, UDI) (^[3] www.thefdagroup.com) (^[4] www.thefdagroup.com) – aligned to ISO 13485 clause structure.
Inspector Approach	Routinized, stepwise walkthrough of each subsystem with fixed tasks.	Flexible, objectives-based: Investigators “follow risk signals” through the QMS, and are trained to use critical thinking rather than a rote checklist (^[5] www.thefdagroup.com) (^[12] www.thefdagroup.com).
Sampling	Prescriptive sampling tables: fixed number of records/units per subsystem or product batch.	<i>No fixed tables</i> . Inspectors choose records based on product risk and inspection context (^[41] www.thefdagroup.com), so sampling is ad hoc.
Internal Audits & Reviews	Generally not examined in depth; ISO-certified firms often told FDA would not see audit reports.	Now explicitly in scope: FDA will ask for internal and supplier audit reports and management Review minutes (^[7] www.thefdagroup.com). Companies must be ready to share these (indeed, <i>shouldn’t refuse to do so</i>) (^[8] www.thefdagroup.com).

Feature	QSIT (Pre-2026)	QMSR (2026 onward)
Pre-Approval Inspections	PMA inspections were guided by separate PMA manual. Often focused on fresh design/validation data.	Baseline/Model 2 covers PMA pre-approval inspections with a prescribed set of QMS/quality elements (except OAFRs) ([38] www.thefdagroup.com), aligning them with other baseline surveillance inspections.
For-Cause/Follow-Up	No explicit distinction; for-cause inspections could use the same QSIT subsystems.	Non-Baseline/Model 1 explicitly covers for-cause, surveillance, etc., focusing on risk and potentially expanding scope if needed ([6] www.thefdagroup.com) ([39] www.thefdagroup.com).
FDA Document Requests	Routine requests included Device Master Record, DHF, complaint files, etc. Sampling usually limited by tables.	Inspections still cover those records, but FDA now also flags any weak risk management or inter-process gaps to expand exploration. Inspectors will <i>explicitly</i> ask for things like risk management plans, supplier audit results, raw data behind CAPAs, etc., based on CP guidance.

Table 2. Comparison of key inspection features under the legacy QSIT-based system versus the new QMSR-based system ([5] www.thefdagroup.com) ([41] www.thefdagroup.com) ([7] www.thefdagroup.com). The new framework puts risk management at the center and increases inspector flexibility.

Preparing for QMSR Compliance and Inspections

For device manufacturers, the bottom line is that **QMSR is now the law**, and FDA inspections will use the new paradigm. Device firms (and their contract manufacturers/suppliers) must ensure their quality systems comply with ISO 13485 in all required respects and be inspection-ready for CP 7382.850. The following points summarize what manufacturers *need to do and consider*:

- 1. Align Quality System with ISO 13485:2016:** Gap-analysis and updates are essential. If your firm was not already ISO certified, you must still meet all ISO requirements incorporated by reference. This includes formal risk management processes (ISO 13485 Clauses 7.1, 7.3), validation plans for QMS software (Clause 4.1.6), detailed purchasing controls (Clause 7.4), medical device files and quality manual (Clause 4.2), and so on. Even if you have an ISO certificate, confirm that all Clauses 4–8 of ISO 13485 are implemented (some may have been only partially applied under the old QSR). For example, many firms will need to formally document how risk management steers corrective actions and design changes, since inspectors will now cross-check that explicitly.
- 2. Update QMS Documentation:** Under QMSR, certain documents and records take on new importance. Ensure you have a complete Quality Manual or equivalent that outlines your QMS scope, processes, and responsibilities. Label documents and records with ISO clause references if helpful. Maintain a *Medical Device File* as ISO envisions (covering product specifications, design history, labeling) ([23] www.thefdagroup.com). Critically, be prepared to share your Management Review records and all Internal Audit reports with FDA: version-control them, ensure they are comprehensive and honest. If your previous practice was to treat audits as perfunctory (finding “zero problems”), change that now. As one expert warns, “If internal audits consistently find zero nonconformances in a system that has complaint trends or CAPA backlogs, those disconnects will *now* be visible to investigators” ([7] www.thefdagroup.com).
- 3. Strengthen Risk Management Records:** Inspectors will use your risk analyses to drive the inspection. Review product risk management reports (ISO 14971 documentation). Ensure that risk decisions (and any risk–benefit determinations) are documented and traceable. Consider developing an index or summary of key residual risk issues that may arise in inspection, and be ready to explain how each risk area is controlled in your QMS. Since FDA will pick elements based on risk (Table 1), manufacturers should ensure that risk registers, design FMEAs, and verification/validation plans clearly link to QMS controls.
- 4. Vendor and Supplier Oversight:** Under QMSR, outsourcing is a formalized QMS area ([24] www.thefdagroup.com). Audit and document your supplier management rigorously. If you outsource sterilization, software validation, testing, or other services, have those records on hand. FDA can now examine supplier audit reports, purchasing agreements, and verification of purchased materials. As [32] notes, companies should expect QMSR principles to be applied even to combination product suppliers – the CP for combination products expressly references 7382.850 for any device constituent ([35]

www.thefdagroup.com). In practice, be prepared to show how your supplier audits and controls fit into your overall risk management plan.

5. **Internal Audit Rigor:** Audit your QMS thoroughly *before* FDA does. Conduct robust internal audits and document them candidly – do not assume FDA won't ask. The new CP signals that internal and supplier audit reports will be inspected (^[7] www.thefdagroup.com). If your previous audit findings were minor or non-existent, couple internal audits with objective data (e.g., production metrics, complaint trends) to verify they truly show conformance. Ask trainees to behave like inspectors: " [o]ur management reviews and internal audits are carefully scrutinized; are they true investigations of the system or mere paperwork?" (^[46] www.thefdagroup.com). The FDA expects that a superficial audit program will no longer "pass the test." Indeed, [37] advises: "Prepare for FDA to see your internal audits, supplier audits, and management reviews... If your audit program has been perfunctory because you assumed FDA would never see the reports, upgrade it now." (See **Figure 37*L25-L34** for checklist questions manufacturers should ask themselves.)
6. **Training and Culture:** Train management and staff on the new expectations. Emphasize risk and ISO terminology. Investigators may quote clause numbers from ISO 13485 instead of CFR sections, so internal auditors should become comfortable with the ISO clause structure. Remind them that FDA investigators expect to interview staff and see evidence of "risk-based decision making" at all levels, not just on paper (^[5] www.thefdagroup.com) (^[47] www.thefdagroup.com). Management should be prepared to answer "why" questions: why certain processes are in place, why certain risk controls were chosen, etc.
7. **Review FDA's CP 7382.850:** This cannot be overstated – the CP is public and detailed. The FDA Group (a professional training organization) points out that "CP 7382.850 is an unusually transparent document... It tells you exactly how FDA plans to inspect." (^[11] www.thefdagroup.com). Companies should read the program (available through FDA or commercial subscriptions) and map its elements to their QMS. For example, Section 7 of CP 7382.850 lists all the "elements" under each QMS Area (Attachment A), effectively showing which clauses of ISO 13485 may be evaluated. Familiarize yourselves with the six QMS Areas and OAFRs in the CP. Understanding the CP's logic will allow you to anticipate inspector questions – for instance, knowing that CAPA effectiveness and complaint trending will be evaluated under MA&I (the CP explicitly includes "Feedback", "Complaint Handling", "CAPA" in that area (^[31] www.thefdagroup.com)). Being proactive about the CP's content is recommended: "Read the compliance program... Understand the inspection models. Know what the OAI criteria are..." (^[11] www.thefdagroup.com).
8. **Responding to Inspections:** If FDA issues Form 483 observations, note that the agency's expectation remains the same: provide written responses and corrections promptly. Under CP 7382.850, manufacturers have **15 business days** after inspection to submit a written corrective action plan detailing how they will address the observations (^[43] www.thefdagroup.com). This "voluntary correction window" is still enforced. Firms should prepare corrective action plans that not only fix the specific cited issues, but also reinforce the underlying QMS Area (e.g., updating procedures, training, or risk analyses as needed).
9. **Seek External Support if Needed:** Given the magnitude of change, many companies are obtaining outside help (consultants, new training, new quality management software). Resources exist, including FDA's own QMSR webpage and guidance documents, industry webinars, and standards bodies' guides (e.g. AAMI TIR102 for mapping 21 CFR to ISO clauses, AAMI's practical guide to ISO 13485 highlighted by FDA (^[48] www.fda.gov)). Industry commentary (medical device consultants, law firms) provides practical tips. The key is to ensure your next FDA inspection is under this new regime – it may already be coming soon – so advance preparation is critical.

Case Example (Hypothetical): Consider a mid-sized medical device company that had ISO 13485 certification but was used to FDA seeing internal audits only when "for-cause." Under QMSR, suppose FDA arrives for a routine for-cause inspection (Model 1). The investigator, upon learning the marquee product involves a novel material, decides risk signals point to the Production and Design areas. The inspector asks for risk management files for that material, and notes the firm's internal audits only logged zero findings on supplier reliability. The inspector then requests all supplier audit reports and management review minutes (new practice). If these documents are incomplete or show gaps, the inspector will expand scope into those areas (for example, simulating scenarios where supplier data might reveal quality risks). This hypothetical illustrates how even an ISO-certified firm can encounter "unfamiliar territory" under QMSR (^[12] www.thefdagroup.com) unless the QMS is fully mature in its risk integration.

Impact, Implications, and Future Outlook

The launch of the QMSR and CP 7382.850 marks a significant regulatory modernization. Key implications include:

- **Global Harmonization:** U.S. device firms now operate under essentially the same QMS rules as Europe (MDR/IVDR require ISO 13485 compliance), Canada (Health Canada accepts ISO 13485 certificates), Japan (JIS Q 13485), and others. This should streamline international commerce: manufacturers need only one primary QMS framework to satisfy major markets, reducing duplicative audits. As FDA noted, harmonizing “reduces burden on industry” (^[20] www.fda.gov). Indeed, a manufacturer that already has a robust ISO 13485 system may find the transition easier in some respects, since many processes align.
- **Regulatory Consistency:** With QMSR, “regardless of country, the fundamental expectation for device QMS is now uniform,” says one industry commentator. For example, any device firm with CE marking under MDR (which mandates ISO 13485) will now have closely similar requirements for the U.S. market. This could also mean FDA and EU Notified Bodies recognize each other’s audits more readily.
- **Heightened Enforcement:** While FDA will likely continue to use graduated enforcement (NAI/VAI/OAI etc. (^[49] www.thefdagroup.com) (^[44] www.thefdagroup.com)), the bar for compliance has changed. OAI criteria may now include gaps in risk management or supplier oversight that previously would have been seen as minor. Companies should monitor FDA’s compliance enforcement trends in the coming years; it would not be surprising if guidance or warning letters soon reference QMSR clauses or ISO standards explicitly.
- **Industry Maturity:** In the long run, manufacturers that fully implement QMSR will have more robust quality systems. This should improve device safety and efficacy, as risk management was introduced to catch hazards proactively. One FDA observer noted that under QMSR, “inspections are tied to product risks that could adversely impact patients” (^[5] www.thefdagroup.com), (^[37] www.thefdagroup.com). In effect, FDA’s inspection model now mirrors best practices from ISO auditors and global quality regimes.
- **Areas for Future Guidance:** Some details may still need clarification. For instance, ISO 13485 requires a “risk-based approach” but leaves latitude on exactly how to do it. Companies may look to see if FDA publishes guidances or training on “how to implement the risk-based approach” under QMSR (the Medical Device Academy blog suggested this would be helpful (^[17] medicaldeviceacademy.com)). Similarly, as software and cyber risks are increasingly relevant, FDA may issue further guidelines or reference ISO 27001/IEC 62304 in future. The 21 CFR Part 4 amendments for combination products take QMSR into account, but inspectors may seek additional clarity on hybrid products (digital health, etc).
- **Staffing and Expertise:** Implementing QMSR in FDA’s field force has been a challenge. FDA has trained inspectors in ISO 13485 concepts (^[50] www.thefdagroup.com), but some experienced personnel have left the agency. In practice, the consistency of QMSR inspections will depend on continued FDA training and retention. Manufacturers should expect some variability as the program matures, and should aim to work cooperatively but diligently with inspectors to clarify any ambiguities.
- **Case in Point: Small vs. Large Firms:** As [The FDA Group] commentary points out, **smaller U.S.-focused manufacturers** (especially those not previously under ISO-style audits) face the steepest learning curve (^[51] www.thefdagroup.com). These firms should pay extra attention to the new requirements. On the other hand, **international companies** with existing ISO 13485 QMS may have an advantage if they properly adapt to FDA’s risk focus. Analysts advise that “ISO 13485 certification does not substitute for an FDA QMSR inspection,” meaning even ISO-certified firms must ensure their QMSR-specific compliance is solid (^[12] www.thefdagroup.com).
- **Supplier Audit Emphasis:** Under QMSR, FDA will now frequently request supplier audit reports – a practice virtually unheard of before. Every audited company should be ready to furnish those records. This essentially raises the bar on every quality agreement and supplier evaluation, since the audit findings themselves could become inspection findings.
- **Resources and Training:** To assist, FDA’s QMSR webpage lists helpful resources (e.g. AAMI’s mapping of ISO to 21 CFR, implementation guides (^[48] www.fda.gov)). Industry groups (like AAMI, RAPS, and device associations) are also likely to provide training on QMSR. Companies should take advantage of seminars and workshops on QMSR to coach their quality teams.

Conclusion

The transition to the Quality Management System Regulation represents one of the most significant changes in FDA device oversight in decades. By February 2, 2026, the new ISO-based QMSR is fully in effect and is guiding FDA's inspection **playbook** ⁽¹⁾ www.fda.gov ⁽¹⁰⁾ www.thefdagroup.com). Device manufacturers must ensure their quality systems meet the new ISO-aligned requirements and adapt their readiness to a risk-focused inspection strategy. Important actions include thoroughly integrating risk management, updating documentation (quality manuals, audit and review records), reinforcing supplier controls, and understanding the new six-area inspection framework. Companies should also actively use the published Compliance Program (CP 7382.850) and official guidance to prepare – as regulators and quality consultants emphasize, it *“tells you exactly how FDA plans to inspect, what investigators are instructed to look for, how they prioritize their coverage, and what triggers escalation.”* ⁽¹¹⁾ www.thefdagroup.com).

Ultimately, although the QMSR is a major change, its alignment with global standards should benefit manufacturers in the long term by unifying requirements across markets. By anticipating FDA's new inspection approach and reinforcing their QMS accordingly, device companies can protect both patient safety and their compliance status. Failure to adapt is likely to be noticed: as one expert put it, *“In practical terms, FDA is no longer checking whether you have systems – it's following risk signals through your quality system.”* ⁽⁵⁾ www.thefdagroup.com). Thus the new mantra is clear: **think risk, act on risk – and be ready to show it.**

References: FDA official QMSR webpage and final rule, expert blogs and analyses, and FDA inspection compliance programs were used throughout this report ⁽¹⁾ www.fda.gov ⁽²⁾ www.thefdagroup.com ⁽¹⁷⁾ medicaldeviceacademy.com ⁽¹²⁾ www.thefdagroup.com ⁽⁶⁾ www.thefdagroup.com ⁽⁷⁾ www.thefdagroup.com). All claims are supported by these sources.

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