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STANDARDS & GUIDANCE REPORT · UNITED STATES · REGULATION

21 CFR Part 820 (QMSR)

Quality Management System Regulation

DOCUMENT	QES-WP-101, Rev B	DATE	November 7, 2026
ISSUED BY	US Food and Drug Administration	PREPARED BY	Conner Davidson
EDITION	QMSR final rule of February 2, 2024, effective February 2, 2026 (technical amendments December 4, 2025)	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices	ONLINE	qesisbest.com/standard-21-cfr-820.html

IN FORCE In force since February 2, 2026. Part 820 now incorporates ISO 13485:2016 by reference, with clause 3 of ISO 9000:2015 for terms. FDA stopped using the Quality System Inspection Technique (QSIT) the same day and inspects under Compliance Program 7382.850, which replaced 7382.845 and 7383.001. **Next:** No transition period remains. Inspections under Compliance Program 7382.850 are under way.

What It Covers

The quality system requirements for finished medical devices sold in the United States. In place of FDA's own rules for design controls, CAPA and production, Part 820 now points to ISO 13485:2016 and adds a short list of US-specific provisions where the law requires them.

Who It Applies To

Manufacturers of finished devices for the US market, including specification developers, contract manufacturers, remanufacturers, repackagers, and relabelers. Component makers are reached through their customers' purchasing controls rather than directly.

Key Requirements

- ISO 13485:2016 applied as US law; where a clause conflicts with the FD&C Act or FDA regulations, the US requirement controls.
- FDA-specific record content kept in §820.35, including what complaint and servicing records must show and the unique device identifier.
- Device labeling and packaging controls kept in §820.45: labels inspected for accuracy before release, with a record.
- Management review, internal audit, and supplier audit reports are no longer shielded from FDA inspection.
- Risk management throughout the quality system, as ISO 13485 requires, not only in design.

Structure at a Glance

PART	TOPIC	WHAT IT ASKS FOR
§820.1	Scope	Who the regulation covers, and the exemptions.
§820.3	Definitions	Terms used in Part 820; ISO 9000:2015 clause 3 supplies the rest.

PART	TOPIC	WHAT IT ASKS FOR
§820.7	Incorporation by reference	ISO 13485:2016 and ISO 9000:2015 clause 3, made part of the regulation.
§820.10	Requirements for a quality management system	Comply with ISO 13485 clauses 4 to 8, plus the listed FDA-specific requirements.
§820.35	Control of records	Additional content for complaint, servicing and UDI records, and confidentiality.
§820.45	Device labeling and packaging controls	Label inspection and release, kept from the old rule.

What an Auditor Asks to See

- The quality manual and ISO 13485 procedures, with the US-specific clauses of Part 820 mapped in.
- Complaint files showing the MDR reportability decision for each complaint, linked to CAPA and trending.
- Management review and internal audit records, now within an investigator's reach.
- Design and development files, risk management files, and supplier controls proportionate to risk.

Requirements Checklist

Work down the list with the evidence in hand; write where each item is evidenced in the right-hand column.

#	REQUIREMENT	EVIDENCE ON FILE
1	Quality manual updated to name the QMSR and ISO 13485:2016 as the governing requirements.	
2	Procedure index cross-referenced from old Part 820 sections to ISO 13485 clauses; no orphan citations.	
3	Complaint procedure records the MDR decision and rationale for every complaint (21 CFR 803).	
4	Servicing records analyzed as feedback, with links to complaints where they reveal a failure.	
5	UDI recorded in device history and distribution records.	
6	Label inspection before release documented, including who released and when.	
7	Management review and audit reports written to be read by an investigator.	
8	Risk management planned and evidenced across the QMS, not only in design files.	
9	Purchasing controls proportionate to supplier risk, with evidence of evaluation and monitoring.	
10	Software used in the QMS (ERP, spreadsheets, eQMS) validated for its intended use.	
11	Training records show competence on the revised procedures, not attendance alone.	
12	A mock inspection run against Compliance Program 7382.850.	

Implementation Roadmap

1. Map	Crosswalk every procedure, form, and work instruction that cites a Part 820 section to the ISO 13485 clause now in force.
2. Rewrite	Revise the documents that changed in substance first: complaints, records, labeling, management review, audits.

3. Train	Train the people who own those processes, and test that they can apply the revised procedure.
4. Verify	Run an internal audit and a mock inspection against Compliance Program 7382.850; close what it finds through CAPA.

How It Fits With Other Requirements

An ISO 13485 certificate does not replace an FDA inspection, and FDA does not certify. MDSAP audit reports can stand in for routine FDA inspections. Parts 803 (reporting), 806 (corrections and removals), 830 (UDI) and 11 (electronic records) are unchanged and still apply alongside Part 820.

Findings We See Most Often

- Complaint handling that records the customer's words but not the investigation, the MDR decision, or the trend.
- CAPA that closes on retraining without evidence the cause was found or the fix worked.
- Supplier files with an approval and no monitoring since.
- Label control that relies on the printer rather than an inspection someone signs for.

Where Systems Fall Short

- Procedures that still cite section numbers the old regulation had (820.30, 820.100, 820.198) and the new one does not.
- Audit and management review records written on the assumption FDA would never read them.
- A one-time crosswalk on paper, with the forms and the training never updated to match.

How QES helps. A gap assessment against ISO 13485 and the QMSR's US-specific clauses, with every procedure that still cites an old section number listed for rewrite. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. US FDA — Quality Management System Regulation (QMSR) — www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr; eCFR — 21 CFR Part 820 — www.ecfr.gov/current/title-21/part-820; SGS — ISO 13485 vs US FDA QMSR (June 2026) — www.sgs.com/en-us/news/2026/06/2026-fda-qmsr-vs-iso-13485-changes.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.