

QMSR Transition Checklist

For ISO 13485:2016 & 21 CFR 820 QMSs

Target Compliance Date: February 2, 2026

Scope: Specific supplemental requirements for organizations already compliant with ISO 13485:2016 and legacy 21 CFR 820

This checklist identifies the specific delta requirements that must be addressed when transitioning from the legacy Quality System Regulation (21 CFR 820) to the new Quality Management System Regulation (QMSR). Organizations already compliant to ISO 13485:2016 and legacy 820 should focus on these supplemental FDA-specific requirements.

Phase 1: Verbatim Definitions & Implementation

The following definitions from the FD&C Act and 21 CFR 820.3 supersede any definitions found in ISO 13485 or ISO 9000. Organizations must update QMS documentation to reflect these FDA-specific definitions.

1.1 Superseding Definitions (§ 820.3(b))

These definitions replace the corresponding terms in ISO 13485:2016 and ISO 9000:2015:

Term	QMSR / FD&C Act Definition	Implementation Note
Device	"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease." [FD&C Act § 201(h)]	Supersedes the ISO definition of "Medical Device".
Labeling	"All labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." [FD&C Act § 201(m)]	Supersedes the ISO definition of "Labelling". Note the spelling difference.
Manufacturer	"Any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes... contract sterilization, installation, relabeling, remanufacturing, repackaging, or specification development, and initial distributors of foreign entities."	Supersedes the ISO definition. Any entity meeting this definition must comply with QMSR.
Organization	Defined as "manufacturer" per § 820.3(b). Where ISO 13485 refers to "organization," read as "manufacturer" for QMSR purposes.	Critical mapping: ISO "organization" = QMSR "manufacturer".
Implant	"A device that is intended to be placed in a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more."	Supersedes ISO 13485. The 30-day threshold is a critical U.S. distinction.
Rework	"Action taken on a nonconforming product so that it will fulfill the specified requirements before it is released for distribution."	Supersedes ISO 9000. Note the strict "before release" limitation.
Safety & Performance	No verbatim definition provided; this is an interpretation mandate. Per the preamble, "safety and performance" as used in ISO 13485 shall be interpreted as "safety and effectiveness" for FDA purposes.	Must interpret as "Safety and Effectiveness" in all QMS documents.

1.2 Additional Definitions (§ 820.3(a))

These terms are defined in QMSR but are not defined in ISO 13485 or ISO 9000:

Term	Definition / Application
Component	Any raw material, substance, piece, part, software, firmware, labeling, or assembly that is intended to be included as part of the finished, packaged, and labeled device.
Finished Device	Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.
HCT/P Regulated as Device	Human cells, tissues, or cellular or tissue-based products (HCT/Ps) that are regulated as devices under section 201(h) of the FD&C Act.
Remanufacturer	Any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.
FD&C Act	The Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

1.3 Phase 1 Checklist

- Update Quality Manual to reference QMSR definitions hierarchy (FD&C Act → 820.3 → ISO 13485 → ISO 9000)
- Replace "medical device" with "device" where referencing regulatory definitions
- Replace "safety and performance" with "safety and effectiveness" throughout QMS documentation
- Map "organization" references in ISO 13485-based procedures to "manufacturer"
- Verify implant classification using 30-day threshold (not ISO criteria)
- Update Glossary/Definitions section to include § 820.3(a) terms

Phase 2: Enhanced Record Controls (§ 820.35)

Update "Control of Records" procedures to include these FDA-specific mandates. These requirements are in addition to ISO 13485:2016 Clause 4.2.5.

2.1 UDI Documentation Requirements

- Require the Unique Device Identifier (UDI) or Universal Product Code (UPC) to be recorded for every finished device or batch of medical devices in accordance with 21 CFR Part 830.
- Ensure UDI is captured in Device History Records (now "Medical Device Records" or "Batch Records").

2.2 Complaint Record Requirements

Ensure complaint files explicitly include the following to support 21 CFR Part 803 (MDR) compliance:

- UDI of the device involved
- Date complaint was received
- Follow-up results and investigation outcomes
- Determination of whether complaint represents an MDR-reportable event

2.3 Service Record Requirements

If servicing is performed, records must include:

- UDI of the serviced device
- Troubleshooting findings
- Date of service
- Analysis to determine if service activity should be handled as a complaint

2.4 Record Access and Confidentiality

- Document that records stored off-site must be made available to FDA investigators within 1 to 2 working days.
- Establish a process to mark sensitive records as "Confidential" to prevent public disclosure during FOIA requests.

Phase 3: Labeling & Packaging Controls (§ 820.45)

These prescriptive requirements must be integrated into production and release procedures. FDA retained these from legacy 21 CFR 820 because ISO 13485 Clause 7.5.1(e) does not adequately address labeling inspection activities.

3.1 Labeling Verification Requirements

- Document a requirement for visual inspection of labeling before release to ensure accuracy.
- Inspection must verify: correct UDI, expiration date (if applicable), control number, storage instructions, handling instructions, and any additional processing instructions.
- Note: Per FDA guidance, automated readers alone are insufficient; human examination of representative sampling is required.

3.2 Mix-up Prevention Controls

- Establish specific mix-up prevention controls such as physical separation of labeling areas or mandatory line clearance procedures.
- Document labeling and packaging operations procedures per ISO 13485 Clause 7.5.1(e).

3.3 Release Documentation

- Record the date of the labeling inspection in the Device History Record (Medical Device Record/Batch Record).
- Record the identity of the individual(s) performing the inspection.
- Maintain release documentation per ISO 13485 Clause 4.2.5.

Phase 4: Transparency & Audit Strategy

The QMSR broadens FDA access to internal quality performance data. The legacy exemption under § 820.180(c) has been removed.

⚠ CRITICAL CHANGE: Internal audit reports, management review records, and supplier audit reports are NO LONGER EXEMPT from FDA inspection. This exemption existed under legacy § 820.180(c) but is not carried forward into QMSR.

4.1 Audit Record Accessibility

- Revise Internal Audit procedure to reflect that all audit reports are now fully subject to FDA inspection.
- Revise Management Review procedure to reflect that all management review records are now inspectable.
- Revise Supplier Management procedure to reflect that supplier audit reports are now inspectable.
- Review historical audit and management review records for content that may require explanation during inspection.

4.2 Life-Sustaining/Life-Supporting Device Traceability

- Apply the stringent requirements of ISO 13485 Clause 7.5.9.2 to all life-sustaining or life-supporting devices, even if they are not implantable.
- Ensure traceability records for these devices meet the enhanced requirements.

4.3 Training and Mindset Shift

- Train Subject Matter Experts (SMEs) to present evidence through the process-based framework of ISO 13485 clauses rather than the legacy 21 CFR 820 sections.
- Update inspection readiness procedures to reference ISO 13485 clause structure.

Phase 5: § 820.10 Cross-Referenced Regulations

QMSR § 820.10 explicitly requires compliance with additional FDA regulations beyond ISO 13485. Verify that your QMS addresses these linked requirements:

5.1 Medical Device Reporting (21 CFR Part 803)

- Verify MDR procedures are integrated with complaint handling per § 820.35 requirements.
- Ensure MDR-related data points are captured in complaint records.

5.2 Corrections and Removals (21 CFR Part 806)

- Verify CAPA procedures address correction and removal reporting requirements.
- Ensure linkage between nonconforming product procedures and Part 806 reporting.

5.3 Device Tracking (21 CFR Part 821)

- If applicable to your device classification, verify device tracking procedures are in place.
- Ensure traceability records support tracking requirements.

5.4 Unique Device Identification (21 CFR Part 830)

- Verify UDI labeling compliance per Part 830 requirements.
- Confirm UDI is documented in records per § 820.35 requirements.
- Verify GUDID database submissions are current.

5.5 Electronic Records (21 CFR Part 11)

- If using electronic records and signatures, verify Part 11 compliance continues under QMSR.
- Note: Part 11 requirements are unchanged by QMSR.

Phase 6: Documentation & Terminology Updates

Update QMS documentation to reflect QMSR terminology and structure:

6.1 Terminology Changes

Legacy 21 CFR 820 Term	QMSR / ISO 13485 Term	Reference
Device Master Record (DMR)	Medical Device File	ISO 13485 Clause 4.2.3
Design History File (DHF)	Design and Development Files	ISO 13485 Clause 7.3.10
Device History Record (DHR)	Medical Device Record / Batch Record	ISO 13485 Clause 7.5.1
Quality System	Quality Management System (QMS)	ISO 13485 terminology
21 CFR 820 section references	ISO 13485 clause references	Process-based structure

6.2 Documentation Update Checklist

- Create master list of all QMS documents requiring terminology updates.
- Update Quality Manual to reference ISO 13485 clause structure (not legacy 820 sections).
- Update procedure references from 820 sections to corresponding ISO 13485 clauses.
- Update forms, labels, and electronic system field names.
- Revise training materials to reflect new terminology.
- Remove all obsolete 21 CFR 820 references that are no longer applicable.
- Communicate terminology changes to all staff before implementation.

Summary: QMSR Delta Requirements

Phase	Key Focus	QMSR Reference
1. Definitions	Superseding and additional FDA definitions	§ 820.3(a) & (b)
2. Record Controls	UDI, complaints, service records, confidentiality	§ 820.35
3. Labeling Controls	Inspection, mix-up prevention, release documentation	§ 820.45
4. Audit/Review Access	Removal of inspection exemption for audits/reviews	§ 820.180(c) removed
5. Cross-References	Linked FDA regulations (803, 806, 821, 830)	§ 820.10
6. Documentation	Terminology and reference updates	Throughout QMS

Document prepared based on FDA Final Rule published February 2, 2024 (89 FR 7496). For the most current regulatory information, consult the Federal Register and FDA.gov.

This checklist is intended as a practical implementation guide and does not constitute legal or regulatory advice.