QMSR Transition Checklist

From Legacy 21 CFR 820 to QMSR

Compliance Deadline: February 2, 2026

Scope: Organizations compliant with legacy 21 CFR 820 that are NOT currently ISO 13485:2016 certified

Executive Summary

This checklist provides a comprehensive roadmap for transitioning from compliance with the legacy Quality System Regulation (21 CFR 820) to the new Quality Management System Regulation (QMSR), which incorporates ISO 13485:2016 by reference.

For organizations not currently ISO 13485:2016 certified, this transition represents a significant undertaking requiring implementation of ISO 13485:2016 requirements PLUS FDA-specific additions retained in the QMSR.

Refer to AlvaMed's QMSR Transition Guide for an overall plan for transition, FAQs and terminology crosswalk.

Key Differences Requiring Action

Legacy 21 CFR 820	QMSR / ISO 13485:2016
Section-based structure	Process-based approach with clause structure
Risk mentioned primarily in design controls (§820.30)	Risk-based approach required throughout entire QMS
Quality Manual not explicitly required	Quality Manual explicitly required (Clause 4.2.2)
DMR, DHF, DHR terminology	Medical Device File, Design and Development Files, Batch Records
Audit/Management Review records exempt from inspection	ALL records subject to FDA inspection
Computer software validation addressed generally	Explicit QMS software validation requirement (Clause 4.1.6)
Supplier evaluation documented	Supplier monitoring, re-evaluation, and documented criteria required

Phase 1: Project Setup & Gap Analysis

Duration: 4-8 weeks | Priority: Critical | Must complete before proceeding

1.1 Project Initiation

- ☐ Secure executive sponsor with authority to allocate resources and drive organizational change
- ☐ Form cross-functional transition team (Quality, Regulatory, Engineering, Operations, IT)
- ☐ Obtain copies of ISO 13485:2016 and ISO 9000:2015 standards
- ☐ Download and review QMSR Final Rule (89 FR 7496, February 2, 2024)
- ☐ Establish project governance structure and reporting cadence
- ☐ Create project communication plan for stakeholders
- ☐ Establish document repository for transition project

1.2 Gap Analysis - QMS Documentation (ISO 13485 Clause 4)

Compare current QMS against ISO 13485:2016 Clause 4 requirements:

- ☐ Quality Manual - Does one exist? Does it meet Clause 4.2.2 requirements?
- ☐ Medical Device File structure - Map current DMR to Clause 4.2.3 requirements
- ☐ Document control - Compare current procedures against Clause 4.2.4
- ☐ Record control - Compare against Clause 4.2.5 requirements
- ☐ QMS software validation - Assess compliance with Clause 4.1.6
- ☐ Role of organization documented per Clause 4.1.1
- ☐ Risk-based approach to QMS processes per Clause 4.1.2(b)

1.3 Gap Analysis - Management Responsibility (ISO 13485 Clause 5)

- ☐ Management commitment - Evidence of commitment (Clause 5.1)
- ☐ Customer focus - Requirements determined and met (Clause 5.2)
- ☐ Quality policy - Documented and communicated (Clause 5.3)
- ☐ Quality objectives - Measurable and documented (Clause 5.4.1)
- ☐ QMS planning - Documented (Clause 5.4.2)
- ☐ Responsibility and authority - Defined, documented, communicated (Clause 5.5.1)
- ☐ Management representative - Formally appointed (Clause 5.5.2)
- ☐ Internal communication - Processes established (Clause 5.5.3)
- ☐ Management review procedure - Documented with defined intervals (Clause 5.6.1)
- ☐ Management review inputs - All required inputs addressed (Clause 5.6.2)
- ☐ Management review outputs - All required outputs documented (Clause 5.6.3)

1.4 Gap Analysis - Resource Management (ISO 13485 Clause 6)

- ☐ Provision of resources - Process for determining and providing resources (Clause 6.1)
- ☐ Competence procedures - Documented process (Clause 6.2)
- ☐ Training effectiveness evaluation documented and proportionate to the risk associated with the work (Clause 6.2)
- ☐ Infrastructure - Mix-up prevention and orderly handling (Clause 6.3)
- ☐ Work environment documentation (Clause 6.4.1)
- ☐ Contamination control for sterile devices (Clause 6.4.2 if applicable)

1.5 Gap Analysis - Product Realization (ISO 13485 Clause 7)

- ☐ Planning of product realization (Clause 7.1)
- ☐ Determination of requirements related to product per Clause 7.2.1
- ☐ Review of requirements related to product per Clause 7.2.2
- ☐ Communication with customers and regulatory authorities per Clause 7.2.3
- ☐ Design and development files (Clause 7.3.10) vs. current DHF structure
- ☐ Supplier selection criteria based on effect on device quality and proportionate to the risk associated (Clause 7.4.1)
- ☐ Supplier monitoring and re-evaluation procedures (Clause 7.4.1)
- ☐ Purchasing change notification requirements (Clause 7.4.2)
- ☐ Verification of purchased product (Clause 7.4.3)
- ☐ Control of production and service provision (Clause 7.5.1)
- ☐ Cleanliness of product requirements (Clause 7.5.2)
- ☐ Installation activities procedure (Clause 7.5.3) - if applicable
- ☐ Servicing activity analysis requirement (Clause 7.5.4) – if applicable
- ☐ Sterile device requirements (Clause 7.5.5) - if applicable
- ☐ Process validation including software (Clause 7.5.6)
- ☐ Sterilization and sterile barrier validation (Clause 7.5.7) - if applicable
- ☐ Unique device identification (Clause 7.5.8)
- ☐ Traceability procedures (Clause 7.5.9)
- ☐ Customer property protection (Clause 7.5.10) - if applicable
- ☐ Preservation of product (Clause 7.5.11)
- ☐ Control of monitoring and measuring equipment (Clause 7.6)

1.6 Gap Analysis - Measurement, Analysis, Improvement (ISO 13485 Clause 8)

- ☐ General requirements for monitoring/measurement/analysis (Clause 8.1)
- ☐ Feedback procedure documented (Clause 8.2.1)
- ☐ Complaint handling procedure per Clause 8.2.2
- ☐ Reporting to regulatory authorities procedure (Clause 8.2.3)
- ☐ Internal audit procedure - documented intervals (Clause 8.2.4)
- ☐ Monitoring and measurement of processes (Clause 8.2.5)
- ☐ Monitoring and measurement of product (Clause 8.2.6)
- ☐ Nonconforming product controls (Clause 8.3.1)
- ☐ Actions for NC before delivery (Clause 8.3.2)
- ☐ Actions for NC after delivery including advisory notices (Clause 8.3.3)
- ☐ Rework requirements (Clause 8.3.4)
- ☐ Analysis of data procedure (Clause 8.4)
- ☐ Corrective action procedure (Clause 8.5.2)
- ☐ Preventive action procedure (Clause 8.5.3)

1.7 Gap Analysis Deliverables

- ☐ Complete Gap Analysis Report with findings by ISO 13485 clause
- ☐ Requirements Mapping Spreadsheet (820 sections → ISO 13485 clauses)

- ☐ Remediation Priority Matrix (Critical/High/Medium/Low)
- ☐ Resource requirements estimate for each gap
- ☐ Present Gap Analysis findings to management

Phase 2: QMS Framework & Documentation (Clause 4)

Duration: 6-10 weeks | Priority: Critical | Foundation for all subsequent phases

2.1 Quality Manual Development (Clause 4.2.2)

- ☐ Define QMS scope including details of and justification for any exclusions
- ☐ Document the role(s) of the organization under applicable regulatory requirements
- ☐ Create or update Quality Manual to include:
  - ○ QMS scope with exclusion justifications
  - ○ Documented procedures or references to them
  - ○ Description of process interactions
  - ○ Documentation structure outline
- ☐ Establish process-based QMS structure aligned with ISO 13485 clauses

2.2 Medical Device File Structure (Clause 4.2.3)

- ☐ Establish Medical Device File structure for each device type/family containing:
  - ○ General description, intended use/purpose, and labeling including instructions for use
  - ○ Product specifications
  - ○ Manufacturing, packaging, storage, handling, distribution specifications
  - ○ Measurement and monitoring procedures
  - ○ Installation requirements (if applicable)
  - ○ Servicing procedures (if applicable)
- ☐ Map current DMR content to Medical Device File structure
- ☐ Develop transition plan for existing device documentation

2.3 Document Control Updates (Clause 4.2.4)

- ☐ Update document control procedure to address:
  - ○ Review and approval prior to issue
  - ○ Review, update, and re-approval process
  - ○ Change and revision status identification
  - ○ Availability at points of use
  - ○ Legibility and identification
  - ○ External document control
  - ○ Prevention of obsolete document use
  - ○ Retention period meeting regulatory requirements
  - ○ Protection of confidential health information
  - ○ Protection against deterioration and loss

2.4 Record Control Updates (Clause 4.2.5)

- ☐ Update record control procedure to include records within document control requirements
- ☐ Define storage, protection, retrieval, retention, and disposition
- ☐ Address confidential health information protection
- ☐ Address protection against deterioration and loss

2.5 QMS Software Validation (Clause 4.1.6)

NEW REQUIREMENT: ISO 13485 Clause 4.1.6 explicitly requires validation of computer software used in the QMS, proportionate to risk.

- ☐ Inventory all software used in QMS (eQMS, document control, training, CAPA, etc.)
- ☐ Develop or update software validation procedure for QMS software
- ☐ Conduct risk assessment for each QMS software application

- ☐ Validate QMS software applications proportionate to risk
- ☐ Document validation and revalidation criteria for software changes

2.6 Risk-Based Approach (Clause 4.1.2)

SIGNIFICANT CHANGE: Risk must be applied throughout QMS processes, not just design controls.

- ☐ Document risk-based approach to control of QMS processes
- ☐ Integrate risk considerations into process planning and control
- ☐ Establish criteria for risk-based decision making in QMS processes

Phase 3: Management Responsibility (Clause 5)

Duration: 3-5 weeks | Priority: High

3.1 Management Commitment (Clause 5.1)

- ☐ Document evidence of management commitment to QMS development and implementation
- ☐ Ensure top management communicates importance of meeting regulatory requirements
- ☐ Establish quality policy
- ☐ Ensure quality objectives are established
- ☐ Conduct management reviews
- ☐ Ensure availability of resources

3.2 Customer Focus (Clause 5.2)

- ☐ Ensure customer requirements are determined
- ☐ Ensure customer requirements are met with aim of maintaining customer satisfaction

3.3 Quality Policy (Clause 5.3)

- ☐ Review and update Quality Policy to ensure it:
  - ○ Is appropriate to the purpose of the organization
  - ○ Includes commitment to comply with requirements
  - ○ Includes commitment to maintain QMS effectiveness
  - ○ Provides framework for quality objectives
  - ○ Is communicated and understood within organization
  - ○ Is reviewed for continuing suitability

3.4 Quality Objectives (Clause 5.4.1)

- ☐ Establish measurable quality objectives at relevant functions and levels
- ☐ Ensure objectives are consistent with quality policy
- ☐ Include objectives for meeting product requirements

3.5 QMS Planning (Clause 5.4.2)

- ☐ Document QMS planning to meet general requirements (Clause 4.1)
- ☐ Document planning to achieve quality objectives
- ☐ Ensure QMS integrity is maintained when changes are planned and implemented

3.6 Responsibility and Authority (Clause 5.5.1)

- ☐ Define responsibilities and authorities for all personnel affecting quality
- ☐ Document responsibilities and authorities
- ☐ Communicate responsibilities and authorities within organization
- ☐ Document interrelation of personnel who manage, perform, and verify work affecting quality
- ☐ Ensure independence and authority for personnel to perform quality tasks

3.7 Management Representative (Clause 5.5.2)

- ☐ Formally appoint management representative with documented authority for:
  - ○ Ensuring QMS processes are documented
  - ○ Reporting QMS effectiveness and improvement needs to top management
  - ○ Ensuring promotion of awareness of regulatory and QMS requirements

3.8 Internal Communication (Clause 5.5.3)

- ☐ Establish appropriate communication processes within the organization
- ☐ Ensure communication takes place regarding QMS effectiveness

3.9 Management Review (Clause 5.6)

- ☐ Document management review procedure with:
  - Documented planned intervals
  - Record retention requirements
- ☐ Ensure management review inputs include (Clause 5.6.2):
  - a) Feedback
  - b) Complaint handling
  - c) Reporting to regulatory authorities
  - d) Audits
  - e) Monitoring and measurement of processes
  - f) Monitoring and measurement of product
  - g) Corrective action
  - h) Preventive action
  - i) Follow-up actions from previous management reviews
  - j) Changes affecting QMS
  - k) Recommendations for improvement
  - l) New or revised regulatory requirements
- ☐ Ensure management review outputs include (Clause 5.6.3):
  - Improvement of QMS and processes
  - Improvement of product related to customer requirements
  - Changes needed to respond to regulatory requirements
  - Resource needs

⚠ CRITICAL: Management review records are NO LONGER exempt from FDA inspection under QMSR.

Phase 4: Resource Management (Clause 6)

Duration: 3-5 weeks | Priority: High

4.1 Provision of Resources (Clause 6.1)

- ☐ Determine resources needed to implement and maintain QMS
- ☐ Determine resources needed to maintain QMS effectiveness
- ☐ Determine resources needed to meet applicable regulatory and customer requirements
- ☐ Provide determined resources

4.2 Human Resources & Competence (Clause 6.2)

- ☐ Document procedures for establishing competence, providing training, and ensuring awareness
- ☐ Determine necessary competence based on education, training, skills, experience
- ☐ Provide training or take other actions to achieve competence
- ☐ Evaluate effectiveness of training/actions taken, method proportionate to risk
- ☐ Ensure personnel awareness of:
  - ○ Relevance and importance of their activities
  - ○ Their contribution to achieving quality objectives
- ☐ Maintain training records demonstrating competence

4.3 Infrastructure (Clause 6.3)

- ☐ Document infrastructure requirements including:
  - ○ Buildings, workspace, and associated utilities
  - ○ Process equipment (hardware and software)
  - ○ Supporting services (transport, communication, information systems)
- ☐ Establish requirements to prevent product mix-up
- ☐ Establish requirements to ensure orderly handling of product
- ☐ Document maintenance activities when they can affect product quality

4.4 Work Environment (Clause 6.4)

- ☐ Document work environment requirements needed to achieve product conformity
- ☐ Document work environment requirements for personnel health, cleanliness, clothing (as appropriate)
- ☐ For sterile medical devices - document contamination control requirements (Clause 6.4.2):
  - ○ Requirements for control of contamination with microorganisms or particulate matter
  - ○ Maintain required cleanliness during assembly/packaging

Phase 5: Product Realization (Clause 7)

Duration: 8-12 weeks | Priority: Critical | Largest scope of changes

5.1 Planning of Product Realization (Clause 7.1)

- ☐ Document planning output in form suitable for organization's operations
- ☐ Ensure planning determines quality objectives and requirements
- ☐ Establish processes, documents, and resources specific to product
- ☐ Define verification, validation, monitoring, measurement, inspection, test activities
- ☐ Define criteria for product acceptance
- ☐ Determine records needed to provide evidence processes and product meet requirements
- ☐ Integrate risk management per ISO 14971 into product realization

5.2 Customer-Related Processes (Clause 7.2)

5.2.1 Determination of Requirements (Clause 7.2.1)

- ☐ Determine requirements including:
  - Customer-specified requirements including delivery/post-delivery
  - Requirements not stated but necessary for intended use
  - Applicable regulatory requirements
  - User training needed for safe use

5.2.2 Review of Requirements (Clause 7.2.2)

- ☐ Review product requirements before commitment to supply including:
  - Product requirements are defined
  - Contract/order requirements differing from prior expressions are resolved
  - Applicable regulatory requirements are met
  - User training identified (Clause 7.2.1) is available or planned
  - Organization has ability to meet defined requirements
- ☐ Maintain records of reviews and actions arising from reviews
- ☐ Confirm customer requirements before acceptance when not provided in documented form
- ☐ When requirements change, amend documents and inform relevant personnel

5.2.3 Communication (Clause 7.2.3)

- ☐ Plan and document arrangements for communicating with customers regarding:
  - Product information
  - Enquiries, contracts, order handling including amendments
  - Customer feedback including complaints
  - Advisory notices
- ☐ Establish communication with regulatory authorities per applicable requirements

5.3 Design and Development (Clause 7.3)

- ☐ Document procedures for design and development (Clause 7.3.1)
- ☐ Document design and development planning including (Clause 7.3.2):
  - Design and development stages
  - Reviews needed at each stage
  - Verification, validation, design transfer activities at each stage
  - Responsibilities and authorities
  - Traceability methods (outputs to inputs)
  - Resources needed including personnel competence
- ☐ Document design inputs (Clause 7.3.3) including:

- Functional, performance, usability, safety requirements per intended use
- Applicable regulatory requirements and standards
- Risk management outputs
- Information from previous similar designs

☐ Ensure design outputs meet input requirements (Clause 7.3.4)

☐ Conduct design reviews at suitable stages (Clause 7.3.5)

☐ Document verification plans with acceptance criteria (Clause 7.3.6)

☐ Document validation plans with acceptance criteria (Clause 7.3.7)

☐ Document design transfer procedures (Clause 7.3.8)

☐ Document design change control procedures (Clause 7.3.9)

☐ Establish Design and Development Files (Clause 7.3.10):

- Maintain file for each device type/family
- Include/reference records demonstrating conformity to design requirements
- Include/reference records for design changes

5.4 Purchasing (Clause 7.4)

ENHANCED REQUIREMENTS: Supplier management significantly strengthened vs. legacy 820.

☐ Update supplier selection criteria to address (Clause 7.4.1):

- Effect of purchased product on medical device quality
- Risk associated with the medical device
- Proportionate to risk involved and supplier's ability to meet requirements

☐ Establish supplier monitoring procedures (Clause 7.4.1)

☐ Establish supplier re-evaluation procedures at planned intervals (Clause 7.4.1)

☐ Document actions when suppliers fail to meet requirements (Clause 7.4.1)

☐ Maintain supplier evaluation, selection, monitoring, re-evaluation records (Clause 7.4.1)

☐ Update purchasing information to require supplier notification of changes (Clause 7.4.2)

☐ Define type and extent of verification of purchased product, ensuring it is proportionate to the risks associated with the purchased product (Clause 7.4.3)

☐ Document actions when aware of changes to purchased product (Clause 7.3.4)

5.5 Production and Service Provision (Clause 7.5)

5.5.1 Control of Production (Clause 7.5.1)

- ☐ Update control of production procedures to include:
  - Documentation of procedures and methods for control of production
  - Qualification of infrastructure
  - Monitoring and measurement of process parameters and product characteristics
  - Availability and use of monitoring and measuring equipment
  - Defined operations for labelling and packaging
  - Product release, delivery, and post-delivery activities
- ☐ Establish batch/device records with traceability and approval

5.5.2 Cleanliness of Product (Clause 7.5.2)

- ☐ Document cleanliness/contamination control requirements if:
  - Product cleaned prior to sterilization or use
  - Product supplied non-sterile for cleaning prior to sterilization/use
  - Product cannot be cleaned and cleanliness is significant in use
  - Process agents are to be removed during manufacture

5.5.3 Installation Activities (Clause 7.5.3)

- ☐ Document requirements for medical device installation (if applicable)
- ☐ Document acceptance criteria for verification of installation
- ☐ Provide documented requirements when installation performed by external party
- ☐ Maintain records of installation and verification

5.5.4 Servicing Activities (Clause 7.5.4)

- ☐ Document servicing procedures, reference materials, reference measurements
- ☐ Analyze service records to determine if complaint
- ☐ Use service record analysis as input to improvement process
- ☐ Maintain records of servicing activities

5.5.5 Sterile Medical Device Requirements (Clause 7.5.5)

- ☐ Maintain records of sterilization process parameters for each batch
- ☐ Ensure sterilization records are traceable to each production batch

5.5.6 Process Validation (Clause 7.5.6)

- ☐ Document process validation procedures including:
  - Defined criteria for review and approval
  - Equipment qualification and personnel qualification
  - Use of specific methods, procedures, acceptance criteria
  - Statistical techniques with sample size rationale
  - Requirements for records
  - Revalidation, including criteria
  - Approval of process changes criteria
- ☐ Document software validation for production/service software (risk-proportionate)

5.5.7 Sterilization/Sterile Barrier Validation (Clause 7.5.7)

- ☐ Document procedures for validation of sterilization processes
- ☐ Document procedures for validation of sterile barrier systems
- ☐ Validate prior to implementation and following product/process changes
- ☐ Maintain validation records

5.6 Identification and Traceability (Clauses 7.5.8, 7.5.9)

- ☐ Document product identification procedure (Clause 7.5.8)
- ☐ Identify product by suitable means throughout product realization
- ☐ Identify product status with respect to monitoring/measurement requirements
- ☐ Implement unique device identification per Part 830 requirements
- ☐ Document procedures to identify returned medical devices
- ☐ Document traceability procedures (Clause 7.5.9.1)
- ☐ For implantable devices, ensure traceability of (Clause 7.5.9.2):
  - All components, materials, and work environment conditions
  - Identity of personnel performing activities
- ☐ Require distributors to maintain distribution records for traceability (Clause 7.5.9.2)
- ☐ Maintain records of shipping package consignee name and address (Clause 7.5.9.2)

5.7 Customer Property (Clause 7.5.10)

- ☐ Identify customer property provided for use or incorporation
- ☐ Verify customer property
- ☐ Protect and safeguard customer property
- ☐ Report to customer and maintain records if property lost/damaged/unsuitable

5.8 Preservation of Product (Clause 7.5.11)

- ☐ Document procedures for preserving product conformity during:
  - Processing
  - Storage
  - Handling
  - Distribution
- ☐ Apply preservation to constituent parts of medical device
- ☐ Protect product from alteration, contamination, damage by:
  - Designing suitable packaging and shipping containers
  - Documenting special conditions if packaging alone cannot provide preservation
- ☐ Control and record special conditions if required

5.9 Control of Monitoring and Measuring Equipment (Clause 7.6)

MAJOR REQUIREMENT: Comprehensive calibration program with software validation for M&M equipment.

- ☐ Determine monitoring and measurement to be undertaken
- ☐ Determine monitoring and measuring equipment needed
- ☐ Document procedures to ensure monitoring/measurement carried out consistently
- ☐ Ensure measuring equipment is:
  - ○ Calibrated or verified at specified intervals against traceable standards
  - ○ Adjusted or re-adjusted as necessary (with records)
  - ○ Identified to determine calibration status
  - ○ Safeguarded from adjustments that would invalidate results
  - ○ Protected from damage and deterioration
- ☐ Document procedures for calibration/verification
- ☐ Assess and record validity of previous results when equipment found nonconforming
- ☐ Take appropriate action on equipment and affected product
- ☐ Maintain calibration and verification records
- ☐ Document procedures for validation of M&M software
- ☐ Validate M&M software prior to initial use
- ☐ Revalidate M&M software after changes (risk-proportionate approach)
- ☐ Maintain M&M software validation records

Phase 6: Measurement, Analysis & Improvement (Clause 8)

Duration: 4-6 weeks | Priority: High

6.1 General (Clause 8.1)

- ☐ Plan and implement monitoring, measurement, analysis, improvement processes to:
  - Demonstrate conformity of product
  - Ensure conformity of QMS
  - Maintain QMS effectiveness
- ☐ Determine appropriate methods including statistical techniques and extent of use

6.2 Feedback Process (Clause 8.2.1)

- ☐ Document feedback procedure including:
  - Methods for obtaining and using feedback information
  - Provisions to gather data from production activities
  - Provisions to gather data from post-production activities
- ☐ Ensure feedback serves as input into risk management processes
- ☐ Ensure feedback used for monitoring/maintaining product requirements
- ☐ Include review of post-production experience if required by regulations

6.3 Complaint Handling (Clause 8.2.2)

- ☐ Document complaint handling procedure including requirements for:
  - Receiving and recording information
  - Evaluating if feedback constitutes a complaint
  - Investigating complaints
  - Determining need to report to regulatory authorities
  - Handling of complaint-related product
  - Determining need for corrections or corrective actions
- ☐ Document justification when complaints are not investigated
- ☐ Document process for exchanging information with external parties
- ☐ Maintain complaint handling records

6.4 Reporting to Regulatory Authorities (Clause 8.2.3)

- ☐ Document procedure for reporting to regulatory authorities:
  - Criteria for reporting adverse events per applicable regulations
  - Criteria for issuing advisory notices
- ☐ Maintain records of reporting

6.5 Internal Audit (Clause 8.2.4)

- ☐ Document internal audit procedure including:
  - Responsibilities and requirements for planning/conducting audits
  - Requirements for recording and reporting results
- ☐ Plan audit program considering status/importance of processes and prior results
- ☐ Define and record audit criteria, scope, interval, methods
- ☐ Ensure auditor selection provides objectivity and impartiality
- ☐ Ensure auditors do not audit their own work
- ☐ Maintain records of audits and results
- ☐ Ensure timely corrections and corrective actions for detected nonconformities
- ☐ Verify actions taken and report verification results

⚠ CRITICAL: Internal audit records are NO LONGER exempt from FDA inspection under QMSR.

6.6 Monitoring and Measurement of Processes (Clause 8.2.5)

- ☐ Apply suitable methods for monitoring and measurement of QMS processes
- ☐ Demonstrate ability of processes to achieve planned results
- ☐ Take correction and corrective action when planned results not achieved

6.7 Monitoring and Measurement of Product (Clause 8.2.6)

- ☐ Monitor and measure product characteristics to verify requirements met
- ☐ Carry out at applicable stages per planned arrangements and documented procedures
- ☐ Maintain evidence of conformity to acceptance criteria
- ☐ Record identity of person authorizing release
- ☐ Identify test equipment used to perform measurements (as appropriate)
- ☐ Do not release product until planned arrangements satisfactorily completed

6.8 Control of Nonconforming Product (Clause 8.3)

- ☐ Document nonconforming product procedure including (Clause 8.3.1):
  - Controls, responsibilities, authorities for dealing with NC product
  - Process for notifying external parties of NC product
- ☐ Ensure investigation commensurate with nonconformity and regulatory requirements
- ☐ Maintain records of nonconformities, investigations, and rationale for decisions

NC Before Delivery (Clause 8.3.2)

- ☐ Document actions for NC detected before delivery:
  - Take action to eliminate nonconformity
  - Authorize use under concession (with justification and approval)
  - Take action to preclude original intended use
- ☐ Verify conformity after correction
- ☐ Document concession requirements including approval authority

NC After Delivery (Clause 8.3.3)

- ☐ Document actions for NC detected after delivery
- ☐ Document requirements for issuing advisory notices per regulations
- ☐ Maintain records of advisory notices

Rework (Clause 8.3.4)

- ☐ Document rework procedures
- ☐ Perform rework per documented procedures
- ☐ Consider adverse effect of rework on product before authorization
- ☐ Verify product meets acceptance criteria after rework
- ☐ Ensure reworked product meets applicable regulatory requirements
- ☐ Maintain records of rework

6.9 Analysis of Data (Clause 8.4)

- ☐ Document procedures for data collection and analysis
- ☐ Determine appropriate methods including statistical techniques

- ☐ Include analysis of data from (at minimum):
  - Feedback
  - Conformity to product requirements
  - Characteristics and trends of processes and products
  - Suppliers
  - Audits
  - Service reports (as appropriate)
- ☐ Use analysis as input for improvement if QMS not suitable/adequate/effective
- ☐ Maintain records of data analysis results

6.10 CAPA (Clauses 8.5.2, 8.5.3)

Corrective Action (Clause 8.5.2)

- ☐ Document corrective action procedure including:
  - Reviewing nonconformities (including complaints)
  - Determining causes of nonconformities
  - Evaluating need for action to ensure nonconformities do not recur
  - Planning, documenting, implementing action (including updating documentation)
  - Verifying action does not adversely affect regulatory compliance or safety/performance
  - Reviewing effectiveness of corrective action
- ☐ Ensure corrective actions proportionate to effects of nonconformities
- ☐ Take corrective actions without undue delay
- ☐ Maintain records of investigations and actions taken

Preventive Action (Clause 8.5.3)

- ☐ Document preventive action procedure including:
  - Determining potential nonconformities and their causes
  - Evaluating need for action to prevent occurrence
  - Planning, documenting, implementing action (including updating documentation)
  - Verifying action does not adversely affect regulatory compliance or safety/performance
  - Reviewing effectiveness of preventive action taken
- ☐ Ensure preventive actions proportionate to effects of potential problems
- ☐ Maintain records of investigations and actions taken

Phase 7: QMSR-Specific Additions

Duration: 3-5 weeks | Priority: Critical | These are FDA-specific requirements beyond ISO 13485

These requirements are specific to QMSR and are in addition to ISO 13485:2016 requirements. They are found in 21 CFR 820.3, 820.35, and 820.45.

7.1 QMSR Definitions (§ 820.3)

Update QMS documentation to reflect the QMSR definition hierarchy:

- ☐ FD&C Act definitions supersede all others (device, labeling, etc.)
- ☐ § 820.3(b) definitions supersede ISO 13485/9000 (manufacturer, organization, implant, rework)
- ☐ § 820.3(a) adds terms not in ISO standards (component, finished device, HCT/P, remanufacturer)
- ☐ Interpret "safety and performance" as "safety and effectiveness"
- ☐ Map "organization" in ISO 13485 to "manufacturer" in QMSR
- ☐ Note: "Implant" uses 30-day threshold (U.S.-specific)

7.2 Enhanced Record Controls (§ 820.35)

These requirements supplement ISO 13485 Clause 4.2.5:

Complaint Records

- ☐ Update complaint records to include:
  - UDI of device involved
  - Date complaint was received
  - Follow-up results and investigation outcomes
  - Information required for MDR compliance (21 CFR Part 803)

Service Records

- ☐ Update service records to include:
  - UDI of serviced device
  - Troubleshooting findings
  - Date of service

Device/Batch Records

- ☐ Document UDI for each medical device or batch per 21 CFR Part 830

Record Access and Confidentiality

- ☐ Document that off-site records must be available within 1-2 working days
- ☐ Establish process to mark records as "Confidential" for FOIA protection

7.3 Labeling & Packaging Controls (§ 820.45)

These requirements supplement ISO 13485 Clause 7.5.1(e):

Labeling Inspection

- ☐ Document procedure for inspecting labeling accuracy before release, including:
  - Correct UDI
  - Expiration date (if applicable)
  - Control number
  - Storage instructions
  - Handling instructions
  - Additional processing instructions
- ☐ Note: Human examination required; automated readers alone are insufficient

Mix-up Prevention

- ☐ Establish specific mix-up prevention controls:
  - Physical separation of labeling areas
  - Mandatory line clearance procedures

Release Documentation

- ☐ Record in Batch Record (Note terminology change from Design History Record):
  - Date of labeling inspection
  - Identity of individual(s) performing inspection

7.4 Cross-Referenced Regulations (§ 820.10)

Verify compliance with regulations explicitly referenced in QMSR:

- ☐ 21 CFR Part 803 - Medical Device Reporting (MDR)
- ☐ 21 CFR Part 806 - Corrections and Removals
- ☐ 21 CFR Part 821 - Device Tracking (if applicable)
- ☐ 21 CFR Part 830 - Unique Device Identification (UDI)
- ☐ 21 CFR Part 11 - Electronic Records and Signatures (if applicable)

Phase 8: Training & Implementation

Duration: 4-8 weeks | Priority: Critical | Concurrent with documentation updates

8.1 Training Program Development

- ☐ Develop ISO 13485:2016 overview training for all QMS-affected personnel
- ☐ Develop role-specific training modules:
  - Executive/Management: Clause 5 responsibilities, management review
  - Quality: Full standard, audit techniques, QMSR additions
  - Engineering: Design controls, risk management integration
  - Production: Process controls, documentation requirements
  - Purchasing/Supply Chain: Supplier management requirements
  - Regulatory: Reporting requirements, QMSR specifics
- ☐ Develop risk-based thinking training (applies throughout QMS)
- ☐ Develop QMSR-specific training on FDA additions
- ☐ Develop inspection readiness training (ISO 13485 clause structure)

8.2 Training Execution

- ☐ Train executive management on responsibilities and commitment required
- ☐ Train all personnel whose work affects product quality
- ☐ Conduct training effectiveness evaluations
- ☐ Document all training records per Clause 6.2
- ☐ Train internal auditors on ISO 13485 requirements and audit techniques
- ☐ Train SMEs on presenting evidence using ISO 13485 clause structure

8.3 Implementation Activities

- ☐ Roll out updated procedures in controlled manner
- ☐ Update electronic systems (eQMS, ERP, etc.) as needed
- ☐ Convert existing documentation to new terminology/structure
- ☐ Update forms and templates
- ☐ Notify critical suppliers of QMS changes
- ☐ Update supplier quality agreements as needed

Phase 9: Verification & Go-Live

Duration: 4-8 weeks | Priority: Critical | Must complete before February 2, 2026

9.1 Internal Audit

- ☐ Conduct comprehensive internal audit against ISO 13485:2016 requirements
- ☐ Conduct internal audit against QMSR-specific requirements (820.3, 820.35, 820.45)
- ☐ Document and address all nonconformities
- ☐ Verify effectiveness of corrective actions
- ☐ Review audit results with management

9.2 Management Review

- ☐ Conduct management review of transition status
- ☐ Review all required inputs per Clause 5.6.2
- ☐ Document management review outputs per Clause 5.6.3
- ☐ Obtain management approval for go-live

9.3 Inspection Readiness

- ☐ Conduct mock FDA inspection using ISO 13485 clause structure
- ☐ Verify all records are accessible and organized
- ☐ Verify audit and management review records are inspection-ready
- ☐ Train front-line personnel on inspection response
- ☐ Update inspection SOPs for QMSR/ISO 13485 framework

9.4 Go-Live Verification

- ☐ Verify all mandatory procedures are approved and implemented
- ☐ Verify all personnel training is complete and documented
- ☐ Verify Quality Manual is approved and distributed
- ☐ Verify Medical Device Files are complete for all device types
- ☐ Verify QMSR-specific records are being captured (UDI, complaints, service)
- ☐ Confirm transition completion to management

9.5 Optional: Third-Party Assessment

- ☐ Consider ISO 13485:2016 certification audit (optional but recommended)
- ☐ Consider MDSAP audit if selling in MDSAP participating countries

Document prepared based on FDA Final Rule published February 2, 2024 (89 FR 7496) and ISO 13485:2016.
For the most current regulatory information, consult the Federal Register, FDA.gov, and official ISO standards.

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

