QMSR DESIGN CONTROL READINESS CHECKLIST

A PRACTICAL SELF-ASSESSMENT FOR MEDICAL DEVICE TEAMS

The FDA's Quality Management System Regulation (QMSR) raises expectations for how design controls, risk management, and traceability function in practice. This checklist is designed to help medical device companies quickly assess their readiness and identify areas of potential FDA scrutiny before an inspection does.

Use this checklist to evaluate whether your current design control system is prepared for QMSR enforcement aligned with ISO 13485.

HOW TO USE THIS CHECKLIST

For each statement below, mark:

- ✔ – Fully Implemented
- ? – Partially Implemented / Inconsistent
- X – Significant Gap

1. Medical Device File (MDF) Integrity (Replacing Design History (DHF), Device Master Record (DMR), and Device History Record (DHR))

The Medical Device File replaces disconnected DHF, DMR, and DHR documents with a single, integrated view of design and manufacturing.

- ☐ Design inputs, outputs, verification, and validation are clearly linked within the MDF
- ☐ Risk management records are integrated with design documentation
- ☐ Design outputs including manufacturing process definition are connected to production equipment/ tools, controls, and specifications
- ☐ MDF content reflects the current approved product configuration
- ☐ Evidence can be output quickly with "audit-ready all-the-time" integrity of all the content

QMSR Risk Indicator: Fragmented or legacy DHF/DMR silos slow inspections and signal weak system control.

2. Product Realization and Traceability

Design Traceability must function continuously—not just during audits.

- ☐ Requirements are traceable to risks and mitigations/controls
- ☐ Verification trace of outputs to inputs and validation trace of user need satisfaction
- ☐ Traceability is maintained when designs change
- ☐ Traceability does not rely on manual spreadsheets
- ☐ Missing or broken links are immediately visible

QMSR Risk Indicator: Manual or retrospective traceability signals weak system effectiveness.

3. Risk Management as a Living Process

Risk management must evolve alongside design and real-world use.

- [ ] Risk files are updated when design changes occur
- [ ] Risk controls are verified and validated
- [ ] Postmarket feedback feeds back into risk assessments
- [ ] Risk management acceptance criteria are clearly defined and applied
- [ ] Risk data reflects current product reality

QMSR Risk Indicator: Static risk files suggest risk is documented—not managed.

4. Change Impact Analysis

Design changes must be evaluated holistically across the design control system.

- [ ] Design change impacts on requirements are assessed
- [ ] Risk impacts of design changes are evaluated
- [ ] Verification and validation impacts are identified
- [ ] Change decisions and rationale are documented
- [ ] Downstream impacts are consistently reviewed

QMSR Risk Indicator: Incomplete change impact analysis is a common FDA inspection trigger.

5. Preservation of Design Intent

FDA increasingly evaluates why decisions were made—not just what was approved.

- [ ] Design decisions include documented rationale and key decisions
- [ ] Assumptions and constraints are clearly recorded
- [ ] Design intent is preserved beyond individual contributors
- [ ] Historical design decisions can be explained years later
- [ ] Design knowledge is not trapped in emails or meeting notes

QMSR Risk Indicator: Lost design intent weakens traceability and inspection confidence.

6. Inspection Readiness & System Confidence

Your design control system should support efficient, confident inspections.

- [ ] Design and process evidence can be retrieved quickly
- [ ] Teams can explain system behavior without scrambling
- [ ] Traceability can be demonstrated live during inspections
- [ ] Remediation does not require large-scale document reconstruction
- [ ] Engineering resources are protected during audits

QMSR Risk Indicator: Inspection-driven fire drills indicate systemic design control weaknesses.

SCORING YOUR QMSR READINESS

- Mostly ✔ – Your design control system is well-positioned for QMSR
- Mix of ✔ and ? – Moderate risk; targeted improvements recommended
- Many ✘ – High risk; QMSR enforcement may expose significant gaps

WHAT TO DO IF YOU IDENTIFY GAPS

QMSR readiness is not about last-minute fixes rather it is about building design control systems that scale with complexity and change.

Organizations that proactively address gaps can:

- Reduce risk of FDA inspection findings
- Minimize the need for rework during disruptive remediation activity
- Protect engineering productivity
- Accelerate product commercialization with confidence in the integrity of the Medical Device File

Use this checklist as a starting point to prioritize improvements and guide deeper assessments.

ABOUT COGNITION

Cognition Corporation, headquartered in Lexington, Massachusetts, develops, sells, and supports product development and compliance solutions for the life sciences industry. Its Software-as-a-Service solutions help meet regulations faster with real-time traceability, guided design controls, and change once, update everywhere functionality–turning manual and disconnected data into streamlined, structured submissions that enable them to get to market faster.

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