FDA QMSR

Readiness Checklist | 21 CFR Part 820

Device / role: _____ Reviewer / date: _____

Mark Ready, Gap or N/A. Reference evidence and justify N/A decisions.

1. Scope and applicability | 820.1; 820.10

- ☐ Confirm device classification, manufacturer role, sites and outsourced activities.
- ☐ Document applicable exemptions and design and development requirements.
- ☐ Assign owners for QMSR obligations and required evidence.

2. Implemented quality system | ISO 13485:2016

- ☐ Check management oversight, competence, documented processes and records.
- ☐ Connect risk management with design, suppliers, production and changes.
- ☐ Check nonconformity, corrective action, preventive action and effectiveness evidence.

3. FDA-specific records | 820.35

- ☐ Check complaint information, evaluation, investigation and justified exceptions.
- ☐ Check servicing record details where servicing activities apply.
- ☐ Check required UDI records and record retention, integrity and retrieval.

4. Labeling and packaging | 820.45

- ☐ Control integrity, inspection, storage and labeling/packaging operations.
- ☐ Check identifiers, dates and instructions for accuracy where applicable.
- ☐ Document labeling release and inspection; prevent label and package mixups.

5. Other applicable FDA obligations | 820.10(b)

- ☐ Connect complaint review with Medical Device Reporting under Part 803.
- ☐ Assess corrections/removals under Part 806 and UDI under Part 830.
- ☐ Assess Part 821 tracking and other device-specific obligations where applicable.

6. Inspection evidence and follow-up

- ☐ Prepare records for the current FDA inspection program, 7382.850.
- ☐ Retrieve management review, quality audit and supplier audit evidence.
- ☐ Sample recent work; record gaps, action owners, dates and closure evidence.

Priority gap / evidence reference / owner / target date:

Initial readiness aid, not a complete audit. Confirm applicability against current Part 820, incorporated ISO 13485 requirements and other FDA regulations. Inspection preparation and evidence mapping are implementation tools. Reviewed October 12, 2026.