QMS Implementation & Audit

Medical Device Readiness Checklist

Scope / sites: _____ Reviewer / date: _____

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

1. Scope, requirements and ownership

- ☐ Define device activities, sites, markets and outsourced responsibilities.
- ☐ Identify applicable QMS criteria and assign process owners.
- ☐ Agree the review scope, deliverables and implementation responsibilities.

2. Processes, documents and people

- ☐ Check that approved procedures reflect work performed in practice.
- ☐ Confirm current document access, record retention and change controls.
- ☐ Assess competence and training effectiveness for assigned activities.

3. Implementation evidence

- ☐ Sample records showing applicable design, supplier and production controls.
- ☐ Connect risk controls, acceptance decisions and relevant validation evidence.
- ☐ Check complaints, nonconformities and quality data reach responsible owners.

4. Audit planning and supplier oversight

- ☐ Define audit criteria, methods and risk-based sampling priorities.
- ☐ Confirm competent auditors and arrangements for objectivity and impartiality.
- ☐ Check supplier oversight and follow-up of outsourced process issues.

5. Findings, corrective action and review

- ☐ Link each finding to the criterion, objective evidence and identified gap.
- ☐ Assign corrections, investigation, actions, owners and target dates.
- ☐ Review effectiveness evidence and management review follow-up.

6. Inspection and certification readiness

- ☐ Confirm process owners can explain controls and retrieve consistent evidence.
- ☐ Make management review, quality and supplier audit records retrievable.
- ☐ Use current FDA QMSR inspection information for applicable US activities.

Priority gap / evidence reference / owner / target date:

Planning aid, not a certification or regulatory inspection. Confirm applicability for the device and organization. FDA QMSR has been in force since February 2, 2026. Reviewed October 14, 2026.