QMS Gap Assessment

Scope & Evidence Checklist

Scope / sites: _____ Reviewer / date: _____

Mark Available, Missing or N/A. Reference evidence and justify N/A decisions.

1. Purpose and business context

- ☐ Identify device activities, sites, markets and QMS development stage.
- ☐ Define the assessment objective and decisions it should support.
- ☐ Record scope boundaries, process interfaces and review methods.

2. Criteria and applicability

- ☐ Agree standards, regulations and other requirements included.
- ☐ Document applicability decisions and their supporting rationale.
- ☐ Distinguish ISO 13485 criteria from additional FDA requirements.

3. Documents and implementation evidence

- ☐ Collect current controlled procedures and representative records.
- ☐ Identify process owners and arrange interviews or observations.
- ☐ Flag unavailable evidence and planned but unimplemented controls.

4. Requirement-to-evidence comparison

- ☐ Map selected requirements to documents and implementation records.
- ☐ Distinguish documentation gaps, implementation gaps and evidence needs.
- ☐ Record sampling boundaries and limits on assessment conclusions.

5. Gap register and prioritization

- ☐ Connect each gap with its criterion and supporting evidence.
- ☐ Prioritize by potential impact, dependencies and agreed criteria.
- ☐ Escalate immediate concerns to the responsible management team.

6. Action roadmap and follow-up

- ☐ Agree owners, proposed dates and evidence expected for completion.
- ☐ Separate diagnostic findings from authoring and remediation work.
- ☐ Plan follow-up review and effectiveness checks where applicable.

Priority gap / evidence reference / owner / target date: