Medical Device Internal Audit

Planning & Evidence Checklist

Scope / sites: _____ Reviewer / date: _____

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

1. Scope and audit criteria

- ☐ Define device activities, sites, processes and markets covered.
- ☐ Agree applicable standards, regulations and internal procedures.
- ☐ Record exclusions, selected-process boundaries and program coverage.

2. Planning and auditor assignments

- ☐ Consider process importance, changes, performance and previous findings.
- ☐ Confirm auditor competence, objectivity and relevant experience.
- ☐ Identify conflicts; auditors must not audit their own work.

3. Evidence access and delivery methods

- ☐ Identify required documents, records, process owners and system access.
- ☐ Agree remote, on-site or hybrid methods according to evidence needs.
- ☐ Confirm confidentiality arrangements and the interview schedule.

4. Process trails and sampling

- ☐ Link procedures with interviews, records and observed practice.
- ☐ Sample relevant process interactions and prior corrective actions.
- ☐ Record evidence reviewed and limitations affecting conclusions.

5. Findings and reporting

- ☐ Connect each finding to the criterion, evidence and identified gap.
- ☐ Use the agreed finding classification and reporting procedure.
- ☐ Hold a closing discussion and issue the scoped audit report.

6. Follow-up and management oversight

- ☐ Assign responsibility for corrections and corrective action decisions.
- ☐ Define any agreed evidence review or follow-up audit activities.
- ☐ Retain controlled records and communicate results to management.

Priority gap / evidence reference / owner / target date:

Planning aid for an internal audit; not a certification decision, FDA inspection or formal MDSAP audit. Confirm applicable criteria and record sampling limitations.