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ISO 9001 Readiness

Internal Audit & Certification Preparation

Scope / sites: _____ Reviewer / date: _____

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

1. Scope and audit basis

- ☐ Define activities, sites, products, services and QMS boundaries.
- ☐ Confirm the applicable ISO 9001 edition and certification scope.
- ☐ For existing certificates, confirm transition arrangements with the body.

2. Leadership and planning

- ☐ Assign process owners, responsibilities and escalation routes.
- ☐ Set quality objectives with measures, owners and review dates.
- ☐ Review relevant context, interested parties, risks and opportunities.

3. Resources and operational controls

- ☐ Check competence, resources and current controlled instructions.
- ☐ Review customer requirements, supplier controls and process handoffs.
- ☐ Retain evidence of operational checks and handling of nonconforming outputs.

4. Performance and internal audits

- ☐ Use meaningful process measures and customer feedback.
- ☐ Plan audits around process importance, changes and previous findings.
- ☐ Confirm competent, objective auditors and retain evidence-based reports.

5. Review and improvement

- ☐ Bring relevant performance information into management review.
- ☐ Record decisions, resource needs, owners and follow-up actions.
- ☐ Investigate nonconformities and evaluate corrective action effectiveness.

6. Certification readiness

- ☐ Check implementation evidence against the agreed audit criteria.
- ☐ Prepare process owners to explain controls and retrieve records.
- ☐ Agree assessment arrangements with an independent certification body.

Priority gap / evidence reference / owner / target date:

Planning aid, not a certification decision. Confirm the applicable standard edition and certification body arrangements. ISO 9001 certification does not establish medical device authorization. Reviewed October 13, 2026.