QMS Audit Readiness

People & Evidence Checklist

Scope / sites: _____ Reviewer / date: _____

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

1. Audit scope and priorities

- ☐ Confirm audit type, target dates, sites, activities and markets.
- ☐ Review auditor communications and applicable requirements.
- ☐ Agree readiness review boundaries and preparation priorities.

2. Evidence access and control

- ☐ Identify current procedures and representative implementation records.
- ☐ Test record retrieval, access permissions and version control.
- ☐ Include management review, quality audit and supplier audit records.

3. People and process explanations

- ☐ Assign process owners, deputies and subject matter contacts.
- ☐ Rehearse factual explanations linked to supporting evidence.
- ☐ Confirm staff know how to escalate questions they cannot answer.

4. Previous findings and open actions

- ☐ Review previous findings and supporting closure evidence.
- ☐ Check corrective action status and effectiveness evidence as applicable.
- ☐ Assign owners and dates to unresolved readiness concerns.

5. Audit logistics and request handling

- ☐ Set up a document request log and designated coordination roles.
- ☐ Confirm meeting arrangements, remote access and site availability.
- ☐ Agree daily debriefs and escalation routes for emerging concerns.

6. Management oversight and follow-up

- ☐ Debrief management on review scope, samples and limitations.
- ☐ Prioritize outstanding actions by risk and available preparation time.
- ☐ Schedule a follow-up checkpoint and retain controlled records.

Priority gap / evidence reference / owner / target date: