QMS Governance & Documentation

Ownership & Document Control Checklist

Scope / sites: _____ Reviewer / date: _____

Mark Ready, Action or N/A. Reference evidence and assign the next action.

1. Management controls

- ☐ Confirm QMS responsibilities, approval authority and escalation routes.
- ☐ Prepare management review inputs and retain decision records.
- ☐ Assign owners and follow-up dates to management review actions.

2. Quality planning

- ☐ Link quality objectives to defined activities and responsible owners.
- ☐ Maintain a QMS calendar with agreed reviews and deliverables.
- ☐ Assess how planned changes affect the quality system.

3. Document and record control

- ☐ Identify current revisions, approvals and effective status.
- ☐ Control external documents, distribution and obsolete copies.
- ☐ Define record identification, retrieval, protection and retention.

4. Electronic QMS and data integrity

- ☐ Review intended use, access roles and electronic approval controls.
- ☐ Assess applicable validation and electronic-signature requirements.
- ☐ Confirm change history, backup and record retrieval arrangements.

5. Training and competency management

- ☐ Link role requirements and document changes to training needs.
- ☐ Retain assignments, completion and competence evidence as needed.
- ☐ Define effectiveness checks appropriate to the work performed.

6. Resource and infrastructure management

- ☐ Identify infrastructure, environment and resource responsibilities.
- ☐ Maintain applicable maintenance and contamination-control records.
- ☐ Escalate resource gaps and track management decisions.

Priority action / evidence reference / owner / target date: