Ongoing QMS Controls

Ownership & Evidence Checklist

Scope / sites: _____ Reviewer / date: _____

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

1. Governance and documentation

- ☐ Confirm process owners, controlled documents and record locations.
- ☐ Check training, management review and resource follow-through.

2. Design and risk management

- ☐ Link design and development records to current product configuration.
- ☐ Review relevant risk feedback and specialist lifecycle interfaces.

3. Supplier and purchasing controls

- ☐ Check supplier status, purchasing requirements and quality agreements.
- ☐ Track supplier changes, performance and corrective actions.

4. Production and process quality

- ☐ Check current instructions, acceptance records and product traceability.
- ☐ Review applicable validation, equipment and preservation controls.

5. CAPA and nonconformance management

- ☐ Assign investigation, containment and action responsibilities.
- ☐ Retain implementation and effectiveness evidence as applicable.

6. Complaint and post-market quality

- ☐ Check intake, investigation, trending and reporting decision records.
- ☐ Link relevant feedback to risk review, CAPA and field-action processes.

7. Change and lifecycle quality

- ☐ Assess quality and regulatory impacts before implementing changes.
- ☐ Track relevant requirement updates and new-market QMS actions.

8. QMS performance and improvement

- ☐ Review meaningful quality metrics, audit inputs and overdue actions.
- ☐ Assign owners, dates and evidence for the next improvement priorities.

Priority action / evidence reference / owner / target date: