QMS Health & Maturity

Review Planning Checklist

Scope / sites: _____ Reviewer / date: _____

Mark Reviewed, Follow-up or N/A. Reference evidence and explain limitations.

1. Review purpose and scope

- ☐ Agree the business questions, sites, processes and review period.
- ☐ Identify recent changes, recurring issues and management concerns.
- ☐ Define methods, evidence samples and any maturity descriptors.

2. Ownership and consistent practice

- ☐ Confirm process owners, deputies, responsibilities and handoffs.
- ☐ Compare routine practice with documented expectations.
- ☐ Identify repeated workarounds and dependence on individual knowledge.

3. Quality information and trends

- ☐ Check data definitions, completeness and comparability over time.
- ☐ Review selected complaint, supplier, audit and CAPA trends.
- ☐ Consider workload and reporting changes when interpreting metrics.

4. Decisions and sustained action

- ☐ Trace quality signals through decisions and assigned actions.
- ☐ Review follow-through, recurrence and effectiveness evidence.
- ☐ Identify overdue decisions and escalate significant concerns.

5. Maturity profile and limitations

- ☐ Apply agreed descriptors using documented supporting evidence.
- ☐ Record insufficient evidence without forcing a maturity score.
- ☐ Keep maturity conclusions separate from compliance decisions.

6. Improvement roadmap and follow-up

- ☐ Prioritize actions by potential impact and process dependencies.
- ☐ Agree owners, checkpoints and evidence of sustained progress.
- ☐ Compare follow-up results using consistent scope and definitions.

Priority gap / evidence reference / owner / target date: