Elexes

PERFORMANCE REVIEW / 18 CHECKS

QMS Performance Review Checklist

Connect quality objectives, evidence, decisions and follow-up.

QMS / scope: _____ Reviewer / date: _____

Tick when verified. Reference the evidence and assign the highest-priority action.

01 Set the review scope

- ☐ Identify processes, devices and the review period.
- ☐ Link the review to defined quality objectives.
- ☐ Confirm data owners and review responsibilities.

02 Define the measures

- ☐ Document metric definitions and calculations.
- ☐ Identify sources, denominators and exclusions.
- ☐ Set review frequency and justified response criteria.

03 Check data quality

- ☐ Trace selected results to supporting records.
- ☐ Check completeness, consistency and duplicates.
- ☐ Record limitations or changes in calculation methods.

04 Review the trends

- ☐ Examine complaints, CAPA, audits and other inputs.
- ☐ Consider volume, risk and recurring issues.
- ☐ Document observations and escalation decisions.

05 Agree the response

- ☐ Record decisions, priorities and resource needs.
- ☐ Assign actions, owners and due dates.
- ☐ Link CAPA or controlled changes where appropriate.

06 Verify follow-through

- ☐ Retain evidence of completed actions.
- ☐ Review results against the intended outcome.
- ☐ Carry unresolved issues into the next review.

Priority gap / evidence reference:

Action / owner / due date: