Elexes

18 EVIDENCE CHECKS

CAPA & Nonconformance Review Checklist

From a defined problem to a supported closure decision.

CAPA / NC reference: _____ Reviewer / date: _____

Tick when evidence is verified. Record your priority gap and next action below.

01 Define the issue

- ☐ State the unmet requirement and objective evidence.
- ☐ Identify affected product, processes and source records.
- ☐ Assess risk and document the CAPA escalation decision.

02 Contain and correct

- ☐ Control affected stock, activity and potential wider scope.
- ☐ Record correction, disposition and authorized decisions.
- ☐ Assess relevant risk and regulatory reporting interfaces.

03 Investigate the cause

- ☐ Use an investigation method suited to the issue.
- ☐ Support causes and contributing factors with evidence.
- ☐ Examine why existing controls failed to detect or prevent it.

04 Plan and implement

- ☐ Link actions to causes; assign owners and due dates.
- ☐ Assess changes and potential adverse effects before use.
- ☐ Retain implementation, training and validation evidence as needed.

05 Check effectiveness

- ☐ Define measurable criteria, method and review period.
- ☐ Review suitable data against the intended outcome.
- ☐ Escalate ineffective actions and document the next steps.

06 Close and learn

- ☐ Retain review results, approval and closure rationale.
- ☐ Link trends, complaints, suppliers and related CAPAs.
- ☐ Update affected records and management review inputs.

Priority gap / evidence reference:

Action / owner / due date: