

CAPA that actually closes

Five steps that keep corrective and preventive actions from being reopened. Tick every box before you sign the CAPA closed.

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1 Contain and define Stop the bleeding, then state the facts

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| ☐ Problem stated as facts: what, where, when, how many | ☐ Requirement breached is named (clause, spec, procedure) |
| ☐ Immediate containment done and recorded (hold, quarantine, stop-work) | ☐ Scope checked: other lots, sites or suppliers affected? |

2 Find the real root cause Evidence, not opinion

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| ☐ Method used and recorded (5 Whys, fishbone, fault tree) | ☐ Cause confirmed with data or a test, not a meeting vote |
| ☐ "Human error" taken one level deeper: why was the error possible? | ☐ Someone who actually does the work was on the team |

3 Plan actions that remove the cause Not the symptom

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| ☐ Every action traces to a verified root cause | ☐ One owner and one due date per action |
| ☐ "Retrain" accepted only if training was the cause | ☐ Change control applied to procedures, forms and drawings |

4 Implement and verify Show it, don't say it

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| ☐ Objective evidence for each action (revised document, record, photo) | ☐ Verified by someone other than the action owner |
| ☐ Affected people informed; superseded revisions withdrawn | ☐ Related risks and FMEAs updated |

5 Prove it worked, then close Effectiveness is the finish line

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| ☐ Effectiveness criterion set in advance (e.g. zero repeats in 3 months) | ☐ Effectiveness check done after that window, with data |
| ☐ Lesson applied to similar processes, suppliers and sites | ☐ Closed by the quality function, not the action owner |

Red flags an auditor will spot

CAPA closed the same week it opened · root cause = "human error" · the only action is "retrain"
· no effectiveness date · the same nonconformance appears again within a year.