FREE CORRECTIVE AND PREVENTIVE ACTION TEMPLATE

CAPA Checklist

Use this 60-point checklist to manage CAPA from the source issue through containment, investigation, root cause, action planning, implementation, effectiveness verification, trend review, and final closure.

CAPA / reference	Date opened	CAPA owner	Quality reviewer

1. CAPA intake, source, scope, priority, and ownership

1 Confirm the CAPA reference, site, department, process, product or service, initiation date, initiator, process owner, and quality owner.

CAPA CONTROL

NAME Enter | DATE / TIME Enter | APPROVAL Sign

Execution tip: Start with a clear problem statement and ownership. CAPA quality drops quickly when teams begin with solutions before agreeing on what actually failed.

2 Record the trigger for the CAPA, such as audit finding, non-conformance, complaint, defect trend, supplier issue, incident, deviation, risk review, or management decision.

CAPA CONTROL

CAPA / Scope	Current	Owner	Evidence	Action

Execution tip: Start with a clear problem statement and ownership. CAPA quality drops quickly when teams begin with solutions before agreeing on what actually failed.

3 **Define the problem or improvement need in clear terms, including the requirement, observed condition, affected scope, and why corrective or preventive action is required.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Start with a clear problem statement and ownership. CAPA quality drops quickly when teams begin with solutions before agreeing on what actually failed.

4 **Classify the CAPA using the approved severity, risk, recurrence, customer impact, and urgency method and identify any required escalation.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Start with a clear problem statement and ownership. CAPA quality drops quickly when teams begin with solutions before agreeing on what actually failed.

5 **Review linked records such as NCRs, audit findings, complaints, incidents, batches, supplier issues, service failures, previous CAPAs, or related trend data.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: Start with a clear problem statement and ownership. CAPA quality drops quickly when teams begin with solutions before agreeing on what actually failed.

6 Assign ownership for containment, investigation, root cause, action planning, implementation, effectiveness verification, communication, and final approval.

CAPA CONTROL

CAPA / Scope	Current	Owner	Evidence	Action

Execution tip: Start with a clear problem statement and ownership. CAPA quality drops quickly when teams begin with solutions before agreeing on what actually failed.

2. Immediate correction, containment, risk reduction, and interim controls

7 **Confirm immediate correction has addressed the currently known defect, error, failed output, unsafe condition, customer issue, or process problem where action is required.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: Contain the current risk without confusing containment with permanent corrective action. Temporary controls need owners and an end condition.

8 **Verify containment prevents additional affected product, service, transaction, process output, or customer impact while the CAPA investigation is open.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Contain the current risk without confusing containment with permanent corrective action. Temporary controls need owners and an end condition.

9 **Identify the full potentially affected scope by product, batch, time period, location, customer, supplier, transaction, process step, or operating condition.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Contain the current risk without confusing containment with permanent corrective action. Temporary controls need owners and an end condition.

10 Confirm temporary controls, increased inspection, system blocks, hold status, access restrictions, extra approvals, substitute resources, or other interim measures are clearly defined.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Contain the current risk without confusing containment with permanent corrective action. Temporary controls need owners and an end condition.

11 Check interim controls have named owners, start dates, review dates, evidence requirements, and an end condition so temporary controls do not become permanent by accident.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Contain the current risk without confusing containment with permanent corrective action. Temporary controls need owners and an end condition.

12 **Record evidence that correction and containment are effective and verify the issue is not continuing to escape while root-cause work proceeds.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: Contain the current risk without confusing containment with permanent corrective action. Temporary controls need owners and an end condition.

3. Problem definition, evidence collection, data review, and investigation plan

13 **Write a specific problem statement describing what happened, where, when, how often, how much, and what requirement or expected result was not achieved.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: Collect evidence before deciding the root cause. Compare normal and failed conditions so the investigation is driven by facts rather than assumptions.

14 Collect relevant evidence such as audit records, defect data, complaints, samples, photos, test results, process readings, system logs, equipment history, supplier information, and interviews.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Collect evidence before deciding the root cause. Compare normal and failed conditions so the investigation is driven by facts rather than assumptions.

15 **Separate confirmed facts from assumptions, opinions, suspected causes, and unverified explanations before root-cause analysis begins.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Collect evidence before deciding the root cause. Compare normal and failed conditions so the investigation is driven by facts rather than assumptions.

16 Define the investigation scope, responsible participants, required data, analysis method, milestones, and completion date based on CAPA risk and complexity.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Collect evidence before deciding the root cause. Compare normal and failed conditions so the investigation is driven by facts rather than assumptions.

17 Compare normal and failed conditions, including different shifts, locations, operators, equipment, materials, suppliers, periods, product types, or service cases where relevant.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Collect evidence before deciding the root cause. Compare normal and failed conditions so the investigation is driven by facts rather than assumptions.

18 **Escalate missing data, poor traceability, incomplete evidence, or an unclear affected scope when these gaps prevent a reliable investigation.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: Collect evidence before deciding the root cause. Compare normal and failed conditions so the investigation is driven by facts rather than assumptions.

4. Root cause analysis and contributing-factor verification

19 **Use an appropriate root-cause method to identify why the problem occurred and why existing controls did not prevent or detect it earlier.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: A root cause should explain why the problem occurred and why the existing system did not stop it. Test the cause against the evidence before accepting it.

20 Review potential causes related to process design, people, training, equipment, materials, suppliers, methods, environment, software, communication, workload, and management systems.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: A root cause should explain why the problem occurred and why the existing system did not stop it. Test the cause against the evidence before accepting it.

21 **Distinguish the root cause from the visible defect, immediate error, contributing conditions, and secondary effects of the problem.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: A root cause should explain why the problem occurred and why the existing system did not stop it. Test the cause against the evidence before accepting it.

22 **Test the proposed root cause against evidence and confirm it explains the observed pattern, affected scope, timing, recurrence, and failure mechanism.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: A root cause should explain why the problem occurred and why the existing system did not stop it. Test the cause against the evidence before accepting it.

23 Check whether recent changes in staff, supplier, equipment, software, product, specification, layout, workload, process sequence, or operating conditions contributed to the issue.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: A root cause should explain why the problem occurred and why the existing system did not stop it. Test the cause against the evidence before accepting it.

24 **Document contributing factors separately where they increased likelihood, severity, or detectability but were not the primary root cause.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: A root cause should explain why the problem occurred and why the existing system did not stop it. Test the cause against the evidence before accepting it.

5. Corrective action design, preventive action, risk review, and approval

25 **Define corrective actions that directly address the verified root cause and reduce the likelihood of the same failure recurring.** CRITICAL

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Choose actions that change the control system, not only the behaviour of one person. Reminders and retraining are weak when the underlying process remains unchanged.

26 Identify preventive actions or broader system improvements where the same weakness could create similar failures in other products, processes, locations, suppliers, or teams.

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Choose actions that change the control system, not only the behaviour of one person. Reminders and retraining are weak when the underlying process remains unchanged.

27 **Separate correction, containment, corrective action, and preventive improvement so each part of the CAPA has a clear purpose and closure criterion.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Choose actions that change the control system, not only the behaviour of one person. Reminders and retraining are weak when the underlying process remains unchanged.

28 Assess proposed actions for effectiveness, practicality, resource needs, implementation time, customer impact, safety, compliance, and the risk of creating new problems.

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Choose actions that change the control system, not only the behaviour of one person. Reminders and retraining are weak when the underlying process remains unchanged.

29 **Confirm proposed changes to process, equipment, software, supplier controls, specifications, inspection, training, or documents receive required technical and management approval.** CRITICAL

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Choose actions that change the control system, not only the behaviour of one person. Reminders and retraining are weak when the underlying process remains unchanged.

30 **Reject weak actions that only restate the problem, rely on reminders without addressing the cause, or add inspection where stronger process control is reasonably available.** CRITICAL

CAPA CONTROL

CAPA / Scope	Current	Owner	Evidence	Action

Execution tip: Choose actions that change the control system, not only the behaviour of one person. Reminders and retraining are weak when the underlying process remains unchanged.

6. Action plan, responsibility, deadlines, resources, and escalation

31 **Break the CAPA into specific implementation actions with a named owner, due date, priority, expected result, and objective evidence required for completion.** CRITICAL

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Make every action measurable. A CAPA plan is easier to manage when ownership, deadlines, dependencies, evidence, and escalation are defined up front.

32 **Define dependencies such as engineering changes, supplier response, procurement, system development, validation, training, approval, capital expenditure, or customer communication.** CRITICAL

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Make every action measurable. A CAPA plan is easier to manage when ownership, deadlines, dependencies, evidence, and escalation are defined up front.

33 Confirm resources, budget, people, equipment, external support, and management decisions needed for implementation are available or formally requested.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Make every action measurable. A CAPA plan is easier to manage when ownership, deadlines, dependencies, evidence, and escalation are defined up front.

34 **Set milestones for long-running CAPAs so progress can be reviewed before the final due date and delays become visible early.** CRITICAL

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Make every action measurable. A CAPA plan is easier to manage when ownership, deadlines, dependencies, evidence, and escalation are defined up front.

35 **Define escalation rules for overdue, blocked, high-risk, supplier-dependent, cross-functional, or repeated CAPAs and identify the responsible escalation owner.** CRITICAL

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Make every action measurable. A CAPA plan is easier to manage when ownership, deadlines, dependencies, evidence, and escalation are defined up front.

36 Review the complete action plan for gaps, duplicated actions, conflicting deadlines, unclear ownership, or tasks that cannot be objectively verified.

CAPA CONTROL

CAPA / Scope	Current	Owner	Evidence	Action

Execution tip: Make every action measurable. A CAPA plan is easier to manage when ownership, deadlines, dependencies, evidence, and escalation are defined up front.

7. Implementation, change control, document updates, and training

37 **Verify corrective and preventive actions have been implemented in the actual process, system, equipment, supplier control, or workplace rather than closed at planning stage.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: Implementation should be visible in the real process. Updated documents or completed training alone do not prove the new control is operating.

38 Confirm affected SOPs, work instructions, specifications, forms, checklists, software rules, control plans, visual aids, or approval logic are updated where required.

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Implementation should be visible in the real process. Updated documents or completed training alone do not prove the new control is operating.

39 **Check formal change-control, validation, testing, risk review, authorization, or commissioning requirements are completed before the new control becomes standard practice.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Implementation should be visible in the real process. Updated documents or completed training alone do not prove the new control is operating.

40 Verify affected employees, contractors, suppliers, or other users receive the required communication, training, briefing, competency check, or revised instructions.

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Implementation should be visible in the real process. Updated documents or completed training alone do not prove the new control is operating.

41 **Confirm obsolete documents, old settings, temporary controls, superseded tools, legacy system rules, and conflicting instructions are removed after implementation.** CRITICAL

CAPA CONTROL

OWNER Enter | DUE DATE Enter | EVIDENCE Record

Execution tip: Implementation should be visible in the real process. Updated documents or completed training alone do not prove the new control is operating.

42 **Record implementation evidence including completion dates, revised documents, system screenshots, training records, equipment changes, supplier responses, and approved changes.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: Implementation should be visible in the real process. Updated documents or completed training alone do not prove the new control is operating.

8. Effectiveness verification, monitoring period, recurrence, and validation

43 **Define the effectiveness measure before CAPA closure, including the expected result, data source, review period, sample size, responsible reviewer, and acceptance criteria.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: Define effectiveness criteria before closure. Use enough operating data to show recurrence risk has actually reduced.

44 **Allow enough time, transactions, batches, shifts, locations, service cases, or operating cycles to determine whether the corrective action is sustained.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Define effectiveness criteria before closure. Use enough operating data to show recurrence risk has actually reduced.

45 **Compare post-implementation performance with the original failure pattern using defect rates, complaints, audit results, process data, rework, downtime, or other relevant measures.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Define effectiveness criteria before closure. Use enough operating data to show recurrence risk has actually reduced.

46 Verify the same or a related problem has not recurred in the affected process and that the new control is being followed consistently.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Define effectiveness criteria before closure. Use enough operating data to show recurrence risk has actually reduced.

47 **Confirm the CAPA has not created new defects, delays, excessive workload, safety risks, customer issues, process bottlenecks, or unintended downstream effects.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Define effectiveness criteria before closure. Use enough operating data to show recurrence risk has actually reduced.

48 **Reopen, extend, or revise the CAPA when effectiveness evidence is insufficient, the problem recurs, the scope was incomplete, or the verified root cause was not fully addressed.** CRITICAL

CAPA CONTROL

Verified | More evidence | Critical gap | EVIDENCE Add

Execution tip: Define effectiveness criteria before closure. Use enough operating data to show recurrence risk has actually reduced.

9. CAPA trend analysis, systemic learning, prevention, and management review

49 **Review CAPA trends by source, severity, root cause, process, product, supplier, location, department, customer impact, overdue status, and recurrence.** CRITICAL

CAPA CONTROL

CAPA / Scope	Current	Owner	Evidence	Action

Execution tip: Trend CAPAs by root cause and recurrence, not only by department. Repeated local issues may point to one broader system weakness.

50 **Identify repeated root causes or control weaknesses that require broader preventive action across multiple locations, teams, products, suppliers, or systems.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Trend CAPAs by root cause and recurrence, not only by department. Repeated local issues may point to one broader system weakness.

51 **Compare CAPA cycle time, overdue actions, implementation delays, recurrence rate, effectiveness failures, and closure quality to identify weaknesses in the CAPA process itself.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Trend CAPAs by root cause and recurrence, not only by department. Repeated local issues may point to one broader system weakness.

52 Confirm lessons learned are incorporated into risk assessments, audit criteria, SOPs, training, supplier controls, control plans, inspection strategies, and quality objectives where relevant.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Trend CAPAs by root cause and recurrence, not only by department. Repeated local issues may point to one broader system weakness.

53 **Review high-risk, overdue, recurring, cross-functional, resource-constrained, or ineffective CAPAs with responsible management at the required frequency.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Trend CAPAs by root cause and recurrence, not only by department. Repeated local issues may point to one broader system weakness.

54 Record management decisions, additional actions, systemic improvement opportunities, resource commitments, and follow-up responsibilities arising from CAPA trend review.

CAPA CONTROL

CAPA / Scope	Current	Owner	Evidence	Action

Execution tip: Trend CAPAs by root cause and recurrence, not only by department. Repeated local issues may point to one broader system weakness.

10. Final review, closure readiness, residual risk, approval, and sign-off

55 **Confirm all approved CAPA actions are complete and supported by the objective evidence defined in the action plan.** CRITICAL

CAPA CONTROL

CAPA / Scope	Current	Owner	Evidence	Action

Execution tip: Close only when actions, evidence, effectiveness, residual risk, and linked source records all support the same conclusion.

56 **Verify required documents, training, system controls, equipment changes, supplier actions, validations, and change-control records are complete and current.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Close only when actions, evidence, effectiveness, residual risk, and linked source records all support the same conclusion.

57 Check containment and temporary controls have been formally removed, transferred, or converted into approved permanent controls where appropriate.

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Close only when actions, evidence, effectiveness, residual risk, and linked source records all support the same conclusion.

58 **Confirm effectiveness criteria have been met, recurrence risk is acceptable, residual risks are documented, and no critical related issue remains unresolved.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Close only when actions, evidence, effectiveness, residual risk, and linked source records all support the same conclusion.

59 **Review linked NCRs, audit findings, complaints, incidents, supplier records, or other source records and confirm their status is consistent with the CAPA closure decision.** CRITICAL

CAPA CONTROL

Complete | In progress | Not complete | N/A

Execution tip: Close only when actions, evidence, effectiveness, residual risk, and linked source records all support the same conclusion.

60 **Record final CAPA status, effectiveness result, residual risk, closure date, next follow-up if needed, CAPA owner, quality reviewer, approver, date, time, and sign-off.** CRITICAL

CAPA CONTROL

NAME Enter | DATE / TIME Enter | APPROVAL Sign

Execution tip: Close only when actions, evidence, effectiveness, residual risk, and linked source records all support the same conclusion.