FREE MANUFACTURING CAPA TEMPLATE

Corrective and Preventive Action Checklist

Use this 60-point checklist to control CAPA from issue intake and containment through scope, root cause, corrective action, preventive risk controls, implementation, effectiveness, records, trend review, and authorized closure.

CAPA ID / source	Initiation date	Process / area	Owner / quality reviewer

Internal manufacturing template. Apply the organization's current CAPA procedure, risk methodology, QMS requirements, customer obligations, change controls, and sector regulations. ISO 9001:2015 integrates prevention through risk-based thinking.

1. Issue intake, problem statement, source, ownership, and CAPA initiation

1 **Confirm the CAPA record identifies the issue source, such as nonconformance, audit finding, complaint, inspection failure, process deviation, supplier issue, incident, trend, or management review.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Start with a factual problem statement. Define what happened, where, when, how often, and what requirement was not met before deciding on a cause...

2 **Verify the problem statement describes the observed condition, affected requirement, location or process, date or period, and objective evidence without assuming the root cause.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Start with a factual problem statement. Define what happened, where, when, how often, and what requirement was not met before deciding on a cause...

3 **Confirm the affected product, material, equipment, process, supplier, customer, lot, batch, serial, site, or shift is identified where applicable.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Start with a factual problem statement. Define what happened, where, when, how often, and what requirement was not met before deciding on a cause...

4 **Verify a CAPA owner and responsible cross-functional team are assigned with the authority and competence needed to investigate and implement action.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Start with a factual problem statement. Define what happened, where, when, how often, and what requirement was not met before deciding on a cause...

5 **Confirm CAPA priority, target dates, escalation expectations, and required approvals are defined according to the organization's procedure.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Start with a factual problem statement. Define what happened, where, when, how often, and what requirement was not met before deciding on a cause...

6 **Record CAPA ID, source, initiation date, problem owner, process owner, quality reviewer, priority, and target closure date.** CAPA

FINAL STATUS | Enter	CAPA OWNER | Enter	QUALITY APPROVAL | Enter

Execution tip: Start with a factual problem statement. Define what happened, where, when, how often, and what requirement was not met before deciding on a cause...

2. Immediate correction, containment, customer protection, and interim controls

7 **Confirm immediate correction addresses the observed nonconforming condition where practical without being mistaken for the root-cause corrective action.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Containment protects the customer and process while investigation continues. Keep temporary controls visible and time-limited so they do not quietly...

8 **Verify potentially affected product, WIP, raw material, equipment, process output, records, or shipments are identified and controlled as needed.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Containment protects the customer and process while investigation continues. Keep temporary controls visible and time-limited so they do not quietly...

9 **Confirm containment defines the affected population using available traceability, production history, inspection data, dates, lots, shifts, equipment, suppliers, or other relevant boundaries.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Containment protects the customer and process while investigation continues. Keep temporary controls visible and time-limited so they do not quietly...

10 **Verify customers, suppliers, regulators, internal functions, or other interested parties are notified when the organization's approved escalation criteria require communication.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Containment protects the customer and process while investigation continues. Keep temporary controls visible and time-limited so they do not quietly...

11 **Confirm interim controls such as additional inspection, segregation, process checks, temporary work instructions, or increased monitoring have named owners and review dates.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Containment protects the customer and process while investigation continues. Keep temporary controls visible and time-limited so they do not quietly...

12 **Verify containment effectiveness is checked before the investigation proceeds and any escape or expansion of scope triggers immediate reassessment.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Containment protects the customer and process while investigation continues. Keep temporary controls visible and time-limited so they do not quietly...

3. Impact assessment, scope, risk, recurrence, and similar-process review

13 **Assess the actual and potential impact on product quality, safety, compliance, delivery, customer requirements, process capability, cost, or other relevant business outcomes.**

CRITICAL | CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Do not investigate only the item that was found. Ask where else the same failure mechanism, process, material, supplier, software, equipment, or...

14 **Confirm the investigation determines whether the issue is isolated, recurring, systemic, or potentially present in similar products, lines, sites, suppliers, equipment, or processes.**

CRITICAL | CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Do not investigate only the item that was found. Ask where else the same failure mechanism, process, material, supplier, software, equipment, or...

15 **Review historical nonconformances, complaints, audit findings, deviations, maintenance records, quality trends, and previous CAPA for related occurrences.**

CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Do not investigate only the item that was found. Ask where else the same failure mechanism, process, material, supplier, software, equipment, or...

16 **Verify risk or priority is reassessed when new evidence changes the potential severity, occurrence, detectability, scope, or customer exposure.**

CRITICAL | CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Do not investigate only the item that was found. Ask where else the same failure mechanism, process, material, supplier, software, equipment, or...

17 **Confirm similar-process or horizontal-deployment review identifies other areas that may need containment, verification, or preventive risk controls.**

CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Do not investigate only the item that was found. Ask where else the same failure mechanism, process, material, supplier, software, equipment, or...

18 **Document the final investigation scope, affected population, unaffected boundaries, assumptions, and evidence supporting the scope decision.**

CRITICAL | CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Do not investigate only the item that was found. Ask where else the same failure mechanism, process, material, supplier, software, equipment, or...

4. Root-cause analysis, contributing factors, evidence, and cause verification

19 **Use an appropriate root-cause method such as 5 Whys, cause-and-effect analysis, fault tree, process mapping, barrier analysis, or another approved method suited to the problem.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: A root cause should explain why the problem occurred and why the existing controls did not prevent or detect it. Test the suspected cause against...

20 **Confirm the investigation considers process, method, material, machine, measurement, environment, people, supplier, software, design, management-system, and control factors as relevant.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: A root cause should explain why the problem occurred and why the existing controls did not prevent or detect it. Test the suspected cause against...

21 **Differentiate the direct cause, contributing factors, detection or escape cause, and systemic or management-system causes where applicable.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: A root cause should explain why the problem occurred and why the existing controls did not prevent or detect it. Test the suspected cause against...

22 **Verify conclusions are supported by objective evidence such as records, observations, measurements, experiments, interviews, data trends, reproductions, or technical analysis.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: A root cause should explain why the problem occurred and why the existing controls did not prevent or detect it. Test the suspected cause against...

23 **Test or challenge the proposed root cause to confirm that removing or controlling it would reasonably prevent recurrence of the defined problem.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: A root cause should explain why the problem occurred and why the existing controls did not prevent or detect it. Test the suspected cause against...

24 **If the root cause cannot be confirmed, document the uncertainty, interim controls, additional investigation required, and rationale for any risk-based action taken.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: A root cause should explain why the problem occurred and why the existing controls did not prevent or detect it. Test the suspected cause against...

5. Corrective action plan, responsibilities, due dates, and change requirements

25 **Confirm each corrective action directly addresses a verified root cause, contributing cause, or control-system weakness identified by the investigation.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Corrective actions should remove or control verified causes, not simply add reminders. Define exactly what will change, who owns it, when it is due,...

26 **Verify the plan distinguishes permanent corrective action from immediate correction, containment, or temporary inspection increases.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Corrective actions should remove or control verified causes, not simply add reminders. Define exactly what will change, who owns it, when it is due,...

27 **Assign each action to a named owner with a realistic due date, required resources, dependencies, deliverables, and escalation path.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Corrective actions should remove or control verified causes, not simply add reminders. Define exactly what will change, who owns it, when it is due,...

28 **Identify required changes to procedures, specifications, control plans, training, equipment, tooling, software, supplier controls, inspection, maintenance, or process design.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Corrective actions should remove or control verified causes, not simply add reminders. Define exactly what will change, who owns it, when it is due,...

29 **Confirm product, process, equipment, software, supplier, validation, or documentation changes follow the organization's approved change-control requirements where applicable.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Corrective actions should remove or control verified causes, not simply add reminders. Define exactly what will change, who owns it, when it is due,...

30 **Define measurable effectiveness criteria and the evidence that will be used to determine whether recurrence has been prevented or reduced to the accepted level.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Corrective actions should remove or control verified causes, not simply add reminders. Define exactly what will change, who owns it, when it is due,...

6. Preventive risk controls, systemic prevention, and horizontal deployment

31 **Identify comparable products, processes, equipment, sites, suppliers, or failure modes where the verified cause or control weakness could create a future issue.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: In ISO 9001:2015, prevention is embedded in risk-based thinking rather than a separate preventive-action clause. Use CAPA learning to reduce...

32 **Confirm appropriate preventive risk controls are selected for similar areas based on evidence, risk, feasibility, and the organization's approved planning process.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: In ISO 9001:2015, prevention is embedded in risk-based thinking rather than a separate preventive-action clause. Use CAPA learning to reduce...

33 **Review risk registers, PFMEA or DFMEA, control plans, inspection plans, maintenance plans, supplier controls, training, and other preventive controls for needed updates.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: In ISO 9001:2015, prevention is embedded in risk-based thinking rather than a separate preventive-action clause. Use CAPA learning to reduce...

34 **Verify horizontal deployment does not copy an action blindly and instead confirms the same cause, risk, or control weakness is relevant in the receiving area.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: In ISO 9001:2015, prevention is embedded in risk-based thinking rather than a separate preventive-action clause. Use CAPA learning to reduce...

35 **Confirm preventive controls have owners, due dates, implementation evidence, and a defined method for verifying that the targeted risk is better controlled.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: In ISO 9001:2015, prevention is embedded in risk-based thinking rather than a separate preventive-action clause. Use CAPA learning to reduce...

36 **Document why additional preventive deployment is or is not required across similar processes, products, sites, suppliers, or systems.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: In ISO 9001:2015, prevention is embedded in risk-based thinking rather than a separate preventive-action clause. Use CAPA learning to reduce...

7. Implementation, training, document updates, validation, and evidence of completion

37 **Confirm planned corrective and preventive risk-control actions are implemented within the approved scope and authorized change process.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: An action is not complete because a task was marked done. Verify the changed process is released, employees are using it, records are updated, and...

38 **Verify revised procedures, work instructions, drawings, specifications, forms, control plans, inspection criteria, or system configurations are approved before use.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: An action is not complete because a task was marked done. Verify the changed process is released, employees are using it, records are updated, and...

39 **Confirm affected employees receive required communication, training, qualification, or competency verification before independently using the changed process.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: An action is not complete because a task was marked done. Verify the changed process is released, employees are using it, records are updated, and...

40 **Verify equipment, tooling, fixtures, software, automation, process parameters, or test methods are commissioned, validated, qualified, or otherwise verified where required.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: An action is not complete because a task was marked done. Verify the changed process is released, employees are using it, records are updated, and...

41 **Check obsolete documents, settings, labels, tooling, software versions, or previous process methods are removed or controlled to prevent unintended reuse.** CRITICAL CAPA

Effective | Needs follow-up | Reopen

LIVE PHOTO | Add

Execution tip: An action is not complete because a task was marked done. Verify the changed process is released, employees are using it, records are updated, and...

42 **Retain objective implementation evidence such as approved documents, training records, photos, system records, work orders, validation results, purchase records, or completed changes.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: An action is not complete because a task was marked done. Verify the changed process is released, employees are using it, records are updated, and...

8. Effectiveness verification, monitoring period, recurrence check, and closure evidence

43 **Confirm effectiveness review occurs after enough time, production volume, audit activity, supplier deliveries, or process cycles have occurred to make the conclusion meaningful.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Effectiveness is the proof that separates CAPA from task completion. Choose a monitoring period and evidence source that are capable of detecting...

44 **Verify the effectiveness check uses the predefined criteria from the CAPA plan rather than creating easier criteria after implementation.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Effectiveness is the proof that separates CAPA from task completion. Choose a monitoring period and evidence source that are capable of detecting...

45 **Review relevant defects, complaints, audit findings, process data, inspection results, yield, rework, scrap, incidents, supplier data, or other recurrence indicators.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Effectiveness is the proof that separates CAPA from task completion. Choose a monitoring period and evidence source that are capable of detecting...

46 **Confirm direct observation or process verification demonstrates that changed controls are actually being followed and remain operational.** CRITICAL CAPA

Effective | Needs follow-up | Reopen

LIVE PHOTO | Add

Execution tip: Effectiveness is the proof that separates CAPA from task completion. Choose a monitoring period and evidence source that are capable of detecting...

47 **If effectiveness criteria are not met, reopen, extend, or escalate the CAPA and reassess root cause, action design, scope, containment, and preventive risk controls.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Effectiveness is the proof that separates CAPA from task completion. Choose a monitoring period and evidence source that are capable of detecting...

48 **Document the effectiveness conclusion, evidence reviewed, monitoring period, reviewer, date, residual risk, and rationale for closure or continued action.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Effectiveness is the proof that separates CAPA from task completion. Choose a monitoring period and evidence source that are capable of detecting...

9. CAPA records, approvals, communication, overdue actions, and data integrity

49 **Confirm CAPA records are complete, legible, attributable, dated, traceable, and retained according to the organization's document and record-control process.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: CAPA records should tell the story from problem to verified result. A reviewer should be able to reconstruct the issue, evidence, decisions, actions, and...

50 **Verify corrections to CAPA records preserve original information and follow approved data-integrity or record-correction practices.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: CAPA records should tell the story from problem to verified result. A reviewer should be able to reconstruct the issue, evidence, decisions, actions, and...

51 **Confirm required quality, process-owner, technical, regulatory, customer, or management approvals are completed at the appropriate investigation and closure stages.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: CAPA records should tell the story from problem to verified result. A reviewer should be able to reconstruct the issue, evidence, decisions, actions, and...

52 **Verify overdue CAPA, overdue effectiveness checks, stalled investigations, and high-risk open actions are visible and escalated through defined management channels.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: CAPA records should tell the story from problem to verified result. A reviewer should be able to reconstruct the issue, evidence, decisions, actions, and...

53 **Confirm significant CAPA learning and permanent process changes are communicated to affected functions, sites, suppliers, customers, or other stakeholders where required.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: CAPA records should tell the story from problem to verified result. A reviewer should be able to reconstruct the issue, evidence, decisions, actions, and...

54 **Check attachments and linked evidence such as nonconformances, complaints, audit records, photos, measurements, change records, training, and verification results remain accessible.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: CAPA records should tell the story from problem to verified result. A reviewer should be able to reconstruct the issue, evidence, decisions, actions, and...

10. CAPA closure, trend analysis, recurring causes, management review, and continuous improvement

55 **Confirm CAPA closure requires completion of approved actions, required implementation evidence, effectiveness verification, and resolution of open product or process risks.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Trend the CAPA system itself. Repeated causes, overdue investigations, ineffective actions, and recurring containment are signals that the...

56 **Review CAPA trends by source, product, process, site, supplier, root cause, defect category, risk level, owner, age, recurrence, and effectiveness outcome.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Trend the CAPA system itself. Repeated causes, overdue investigations, ineffective actions, and recurring containment are signals that the...

57 **Identify repeated root causes, recurring containment, repeat audit findings, repeat complaints, or reopened CAPA that indicate broader systemic weakness.** CRITICAL CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Trend the CAPA system itself. Repeated causes, overdue investigations, ineffective actions, and recurring containment are signals that the...

58 **Confirm quality objectives, risk reviews, process improvements, training priorities, supplier actions, audit plans, or resource decisions are updated when CAPA trends justify change.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Trend the CAPA system itself. Repeated causes, overdue investigations, ineffective actions, and recurring containment are signals that the...

59 **Verify CAPA performance, overdue actions, major recurring issues, effectiveness failures, and systemic risks are included in management review or equivalent leadership oversight where appropriate.** CAPA

CAPA item	Current status	Owner	Evidence	Action

Execution tip: Trend the CAPA system itself. Repeated causes, overdue investigations, ineffective actions, and recurring containment are signals that the...

60 **Record final CAPA status, residual risks, horizontal deployment status, effectiveness result, closure date, CAPA owner, quality reviewer, process owner, and management approval.** CRITICAL CAPA

FINAL STATUS | Enter	CAPA OWNER | Enter	QUALITY APPROVAL | Enter

Execution tip: Trend the CAPA system itself. Repeated causes, overdue investigations, ineffective actions, and recurring containment are signals that the...