CAPA Model Guidelines

1. Recognize the discrepancy

Non-conformance Phase

A. Use CAPA system to record discrepancy details and assign a trackable ID. Recommended data to include is date of occurrence, source, type, responsibility, expected impact, areas of risk, degree of risk, urgency of response.
B. Distribute discrepancy information to relevant participants. Confirm appropriate approvals and authorizations are present to support requested actions.
C. Document and track communications as staff members, outside organizations or other resources are engaged in process .
D. Monitor activities continuously:
   i. Check performance to deadlines.
   ii. Follow up on lagging tasks.
   iii. Review risk assessment.
   iv. Request additional authorizations or resources.
E. Periodically analyze CAPA data, measure KPI's and communicate findings.

2. Document and distribute the required correction response actions

Corrective Action Phase

A. Use CAPA system to document corrective actions with trackable ID. Details in record should include staff assignments, reference to relevant non-conformance, evaluation of risk , identification of urgency, deadlines and authorizations applied. Be aware multiple corrective actions may be necessary for any non-conformance.
B. Distribute corrective action tasks to responsible staff or other resources. Confirm appropriate approvals and authorizations are present to support requested actions.
C. Document and track communications as staff, outside organizations or other resources are engaged in the process.
D. Monitor activities continuously:
   I. Check performance to deadlines.
   ii. Follow up on lagging tasks.
   iii. Review risk assessments.
   iv. Request additional authorizations or resources.
E. Periodically analyze CAPA data, measure KPI's and communicate findings.

3. Create an investigation plan or plans for the requested actions

Root Cause (or "5 Why's") Phase

A. Gather data from original discrepancy information, related corrective actions, CAPA system data analysis, KPI results and cost details. Evaluate risks, costs and scope. Determine priority.
B. Document root cause investigation with Trackable ID and assign to staff members with deadlines. Be aware there may be more than one root cause to pursue concurrently on selected problem, and that outside organizations or resources may be needed to support investigation.
C. Document and track communications as staff members, outside organizations or other resources are engaged in the process.
D. Monitor activities continuously:
   i. Check performance to deadlines.
   ii. Follow up on lagging tasks.
   iii. Review risk assessments.
   iv. Request additional authorizations or resources.
E. Review conclusions, accept/reject recommendations, resubmit for additional investigation.
F. Close out completed investigations with recommendations for prevention.
G. Periodically analyze CAPA data, measure KPI's and communicate findings.

4. Document the recommendations and launch preventative actions

Preventative Action Phase

A. Identify recommended preventive actions with trackable id. Include basis of suggestion, responsible staff, expected time line, cost of failure, cost of prevention, known limitations for scope of work, define objectives for improvement management.
B. Request approval for recommended preventive actions outside of procedure limits. There may be multiple approvals required.
C. Launch new investigations for unapproved actions based on feedback. (Return to Phase 3, root cause)
D. Assign approved actions to staff with deadlines, spending limits and scope definitions.
E. Document communications as staff members, outside organizations or other resources are engaged in the process
F. Monitor activities continuously
   i. Check performance to deadlines.
   ii. Follow up on lagging tasks.
   iii. Review risk assessments.
   iv. Request additional authorizations or resources.
G. Periodically analyze CAPA data, measure KPI's and communicate findings.

5. Define the correction response actions required

Verify Phase

A. Record completion of preventive action.
B. Assign verification of preventive action with trackable ID to staff.
C. Document evidence of completion of preventive action.
D. Collect performance data to determine effectiveness of preventive action.
E. Evaluate submitted data and analyze effectiveness of preventive action to meet objectives for improvement management.
F. Close out completed preventive actions or resubmit for investigation (Return to phase 3 Root Cause) if improvement objectives not met
G. Monitor activities continuously
   i. Check performance to deadlines.
   ii. Follow up on lagging tasks.
   iii. Review risk assessments.
   iv. Request additional authorizations or resources.
H. Periodically analyze CAPA data, measure KPI's and communicate findings

Quality Essentials Suite
https://qualityessentialssuite.com
sales@qualityessentialssuite.com