

Corrective Action / Preventive Action (CAPA)

Phase 1: Problem Identification Summarize and give background to the problem
What is the issue or deviation that has occurred?
How was the problem identified?
Create a problem statement that describes the issue in detail and what exactly needs to occur for the problem to be considered remediated:
What is the scope of the problem and who will be assigned to the investigation?
Phase 2: Impact Assessment and Risk Analysis State the impact that the problem was having on operations
How much does this problem impact operations?
Is the risk level of this issue: <input type="checkbox"/> High <input type="checkbox"/> Medium <input type="checkbox"/> Low
Based on the risk level of this problem the timeline for remediating this issue will be within:
Phase 3: Correction/Containment What action or actions were taken to try to correct the problem?
Phase 4: Investigation/root cause analysis What tools were used to find the root cause and investigate the problem?
Phase 5: Corrective Action & Preventive Action(s) What corrective and preventive actions were put in place as a result of the root cause analysis?



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Phase 6: Implementation

How will the corrective action be implemented permanently, what policies and procedures need to change as a result?

Phase 7: Verification of Effectiveness

What metrics were used to verify the effectiveness?

Metric Used:

How often will the solution be measured to ensure the verification of effectiveness?

Phase 8: Closure

Conclude the CAPA, stating that the corrective action and preventive action taken has remediated the problem

- The corrective action identified has been deemed effective
- Policies and procedures have been updated to prevent re-occurrence
- Regular audits have been established for continued monitoring to ensure the results of the action plan (and solution) have held and maintained control over the initial problem
- Operators have been re-trained on any new policies and procedures as a result of this CAPA

QA Performed By	Operations Reviewed By
Name:	Name:
Signature:	Signature:
Date:	Date:

