

Corrective Action / Preventive Action CAPA FORM



1. Identify the Problem

1.1 How was the problem Identified?

1.2 What is the scope of the problem, and who will be assigned to the investigation?

2. Impact Assessment and Risk Analysis

2.1 State the impact that the contamination is having on the operation.

2.2 How much does this problem impact operations?

2.3 What is the risk level of this issue (could be based on the severity of contamination, location of contamination, or organism type)?

Very Low	Low	Medium	High
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3. Root Cause Analysis

3.1 Materials (Raw Materials)

3.5 Methods (Process)

3.2 Manpower (Personnel)

3.6 Mother Nature (Facility)

3.4 Machine (Facility/Equipment)

3.7 Management (Cleaning & Sanitization)

4. Correction / Containment

4.1 What action/s was taken to try and correct the problem?

4.1.1 Action 1:

4.1.2 Action 2:

4.1.3 Action 3:

5. Corrective Action & Preventive Action(s)

5.1 What corrective and preventive actions were implemented because of root cause analysis?

5.1.1 CAPA 1:

5.1.3 CAPA 3:

5.1.2 CAPA 2:

5.1.4 CAPA 4:

6. Implementation

6.1 How will the corrective action be implemented permanently, and what policies and procedures must change?

7. Verification of Effectiveness

7.1 What metrics were used to verify the effectiveness?

7.1.1 Metric 1:

7.1.2 Metric 2:

7.1.3 Metric 3:

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

8. Completion of CAPA

8.1 Conclude the CAPA, stating corrective & preventive actions have remediated the problem.

The corrective action identified has been deemed effective.

Policies & procedures have been updated to prevent re-occurrence.

Regular audits have been established for continued monitoring to ensure the action plan (and solution) results have held and maintained control over the initial problem.

Investigator Approval

Name: _____

Signature: _____

Date: _____

Closed by Quality Assurance

Name: _____

Signature: _____

Date: _____

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