

Corrective and Preventive Action Planning Table

Audit/Date: _____

Date of CAPA Plan: _____

Preliminary Response Due: _____

Report Prepared by: _____

Completion Instructions:

Auditees are requested to provide information in support of corrections to include identification of finding Root Cause, whether the finding is isolated or systemic and describe corrective and / or preventive action taken.

Definitions:

- Corrective and Preventive Action (CAPA) - Corrective Action is action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence. Preventive Action is action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence
- Effectiveness Verification - The means by which effectiveness of corrective and/or preventive action implementation is verified by a documented and systemic process
- Isolated Audit Finding - An audit finding that can be attributed to human error but does not reflect a systemic/system wide problem.
- Root Cause/Root Cause Analysis (RCA) - is the most basic cause of any undesirable condition or problem, which when eliminated or mitigated will prevent or significantly reduce the effect of the condition or problem
- Systemic Audit Finding - Findings that define a repeating trend or pattern that can be attributed to a root cause

Non-compliance / Potential Non-compliance Identified is as follows:

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Corrective and Preventive Action Planning Table

Finding Number	Noncompliance or Finding:	Root Cause (Systemic or Isolated):	Corrective Action: Preventive Action:	Proposed Completion Date	Actual Completion Date	Responsible Party	Effectiveness Verification

ADD OR DELETE SIGNATORIES AS REQUIRED

GCP Compliance Manager or Designate (signature and date): _____

Reviewed by Vendor's Quality Assurance (signature and date): _____

CLO Manager or Designate (signature and date): _____

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