

ACME COMPANY

CAPA AUDIT CHECKLIST



Millstone Avenue - Rutherford | Millstone Avenue,

MONDAY 11TH AUGUST 2025

SUMMARY

Overall, the CAPA system is effective with strong process controls and documentation. Three improvement areas were identified: role clarity in closures, timely execution despite resource constraints, and more frequent urgent updates.

CAPA Process Understanding

Q#	QUESTION	RESPONSE
1.	Is there clarity on the Corrective and Preventive Action (CAPA) process within the organization?	YES
2.	Are documented policies and procedures available for CAPA implementation?	YES
3.	Are responsibilities clearly defined for initiating, managing, and closing CAPA? Some CAPA closure responsibilities are not clearly assigned in documentation.	NO

Issue Identification and Analysis

Q#	QUESTION	RESPONSE
4.	Is there a structured process for identifying issues or non-conformities?	YES
5.	Are robust methods employed for root cause analysis of identified issues?	YES
6.	Is there proper documentation of identified issues and their root causes?	YES

CAPA Plan Development

Q#	QUESTION	RESPONSE
7.	Are specific action plans developed for addressing identified root causes?	YES
8.	Are realistic timelines established for implementing CAPA actions?	YES
9.	Is there adequate resource allocation for implementing CAPA actions?	YES

Implementation Process

Q#	QUESTION	RESPONSE
10.	Have CAPA actions been executed according to the defined plan? Two CAPA actions were delayed due to unavailability of specialized resources.	NO
11.	Was there effective communication about CAPA actions to relevant stakeholders?	YES
12.	Is there a system in place to monitor the progress of CAPA actions?	YES

Effectiveness Evaluation

Q#	QUESTION	RESPONSE
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13.	Are metrics defined to measure the effectiveness of CAPA actions?	YES
14.	Has the effectiveness of CAPA actions been verified through testing or assessment?	YES
15.	Are established criteria met before closing a CAPA?	YES

Documentation and Records

Q#	QUESTION	RESPONSE
16.	Are records of CAPA activities, changes made, and outcomes maintained?	YES
17.	Is there a reporting mechanism to inform stakeholders about CAPA progress and results? <i>Current reporting frequency does not meet stakeholder expectations for urgent CAPA updates.</i>	NO
18.	Have lessons learned from CAPA implementations been documented?	YES

Continuous Improvement

Q#	QUESTION	RESPONSE
19.	Is there a system to gather feedback on implemented CAPA changes?	YES
20.	Are periodic reviews conducted to assess and adjust CAPA processes?	YES
21.	Are employees adequately trained to implement CAPA actions?	YES

Regulatory Compliance

Q#	QUESTION	RESPONSE
22.	Are CAPA processes aligned with regulatory requirements and standards?	YES
23.	Is there proper documentation showing compliance with regulations?	YES

COMMENTS & ACTION PLAN

CAPA Process Understanding >> CAPA Process Understanding		PRIORITY	High
(AC10055) Are responsibilities clearly defined for initiating, managing, and closing CAPA?		DUE DATE	12 Aug 25
		ASSIGNEE	Jennifer Hunt
FINDINGS	'No' - Some CAPA closure responsibilities are not clearly assigned in documentation.		
ACTION REQUIRED	Update the CAPA procedure to assign closure responsibilities explicitly to roles.		

Implementation Process >> Implementation Process		PRIORITY	Medium
(AC10056) Have CAPA actions been executed according to the defined plan?		DUE DATE	14 Aug 25
		ASSIGNEE	Jennifer Hunt
FINDINGS	'No' - Two CAPA actions were delayed due to unavailability of specialized resources.		
ACTION REQUIRED	Create a resource allocation contingency plan to prevent delays.		

Documentation and Records >> Documentation and Records

(AC10057) Is there a reporting mechanism to inform stakeholders about CAPA progress and results?

PRIORITY High
DUE DATE 13 Aug 25
ASSIGNEE Jennifer Hunt

FINDINGS

'No' - Current reporting frequency does not meet stakeholder expectations for urgent CAPA updates.

ACTION REQUIRED

Implement weekly CAPA progress reporting for high-priority cases.

DECLARATION



Auditor
(Jennifer Hunt)

AUDITOR'S LOCATION