

Corrective and Preventive Action Process Overview

Corrective and Preventive Action (CAPA)

1.0 Definitions¹

- 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

2.0 Introduction¹

CAPA plan is an essential part of a quality audit process. A CAPA plan ensures that upon completion of an audit that audit findings are effectively communicated to the auditee and that findings are addressed and documented in a timely manner.

In general, the CAPA process provides the auditor and auditee with a structured method for the investigation and the follow-up, and resolution of issues identified during the audit process. The CAPA process also serves to provide supporting evidence of audit finding closure and subsequent closure of the audit cycle.

It should be noted that the most effective CAPA process is one that allows the auditee to define their CAPA. The objectivity of the quality assurance and quality auditing process must be maintained; therefore, the auditor or audit team should *not* provide recommendations to the auditee with respect to the CAPA response. Providing such recommendations introduces bias into the quality assurance and quality audit processes.

In summary, the auditees are most familiar with their processes and procedures and are the most qualified individuals to field CAPA responses. Remember, quality assurance and quality audit teams may provide guidance and direction to the auditees but the CAPA process must *not* be directed or mandated solely from the quality audit team's perspective.

3.0 The CAPA Process¹

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The CAPA process includes the following phases: conduct of root cause analysis (RCA) and identification of root cause; description of required corrective and/or preventive actions; effectiveness verification and CAPA closure. (*Refer to Figure 1 and the Corrective and Preventive Action Plan Table*).

3.1 Root Cause and Root Cause Analysis^{1,2}

Root cause analysis (RCA) is required to identify the most basic cause of any undesirable condition (i.e., audit finding). There are several techniques utilized to assist the auditee in identifying root cause, however, the *five (5) whys* technique is most common.

The *5 Whys* is a question-asking method used to explore the cause/effect relationships underlying a particular problem. Ultimately, the goal of applying the *5 Whys* method is to determine a root cause of a defect or problem. The following example demonstrates the basic process:

Example

Problem - My car will not start.

1. *Why?* - The battery is dead. (first why)
2. *Why?* - The alternator is not functioning. (second why)
3. *Why?* - The alternator belt has broken. (third why)
4. *Why?* - The alternator belt was well beyond its useful service life and has never been replaced. (fourth why)
5. *Why?* - I have not been maintaining my car according to the recommended service schedule. (fifth why, a root cause)
6. *Why?* - Replacement parts are not available because of the extreme age of my vehicle. (sixth why, optional footnote)

Solution - I will start maintaining my car according to the recommended service schedule.

The questioning for this example could be taken further to a sixth, seventh, or even greater level which is acceptable. Refer to [English Wikipedia definition of 5 whys](#) or the [Japanese Wikipedia definition for 5 whys](#) for additional information².

3.2 Corrective and Preventive Action¹

Once root cause is defined, the auditee then proceeds to describe how corrective and/or preventive measures will be applied to address the audit finding(s). Remember, not all findings can be subject to both a corrective action or a preventive action. If an issue of non-compliance is identified during an audit

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and, due to circumstances (e.g., too much time has past since the problem occurred) the finding cannot be corrected, then only a preventive measure can be implemented. It also stands to reason that if there is an issue of non-compliance related to a single isolated finding (e.g., a single erroneous entry in a case report form caused by human error) then it is a realistic assumption that only a corrective action can be implemented to close the audit finding.

Once the auditee has defined the CAPA response, the auditee must then define timelines for the completion of the CAPA. The auditee should ensure that realistic timelines for completion of the task at hand are described. Many times inexperienced auditees will describe a time for completion of a CAPA that falls short of the actual time required for implementation. An experienced auditor's quality assurance department can assist the auditee, in this case, by mentoring. Again, care should be taken to ensure that the quality assurance department does not directly instruct the auditee as this will introduce bias into the audit process.

3.3 Effectiveness Verification¹

Once the auditor and the auditee have agreed that the defined CAPA and timelines for completion are acceptable to address the issue(s) of non-compliance, then the CAPA moves towards the final completion phase of the audit cycle: effectiveness verification.

Effectiveness verification is the means by which effectiveness of corrective and/or preventive action implementation is verified by a documented and systemic process, that is, documentation is provided the auditor which represents, to a reasonable degree, that actions taken by the auditee have effectively resolved the audit finding and that the issue will not recur.

An example of an acceptable effectiveness verification may be a copy of an SOP that the auditee created and implemented to resolve an audit finding. The SOP, along with approval dates, signatures and employee training records (which document implementation) will serve to verify effectiveness. *Note: One should avoid an immediate re-audit as a primary means of effectiveness verification as this is impractical due to the resources involved.*

3.4 CAPA Closure¹

When all phases of the CAPA process have been satisfied through documented interaction between the auditor and auditee, and it is verified that the CAPA process and effectiveness of the CAPA have been verified then the CAPA can be designated by the auditor's quality assurance department as *closed*.

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The auditor and the auditee should both maintain records to support the CAPA effort in their official files.

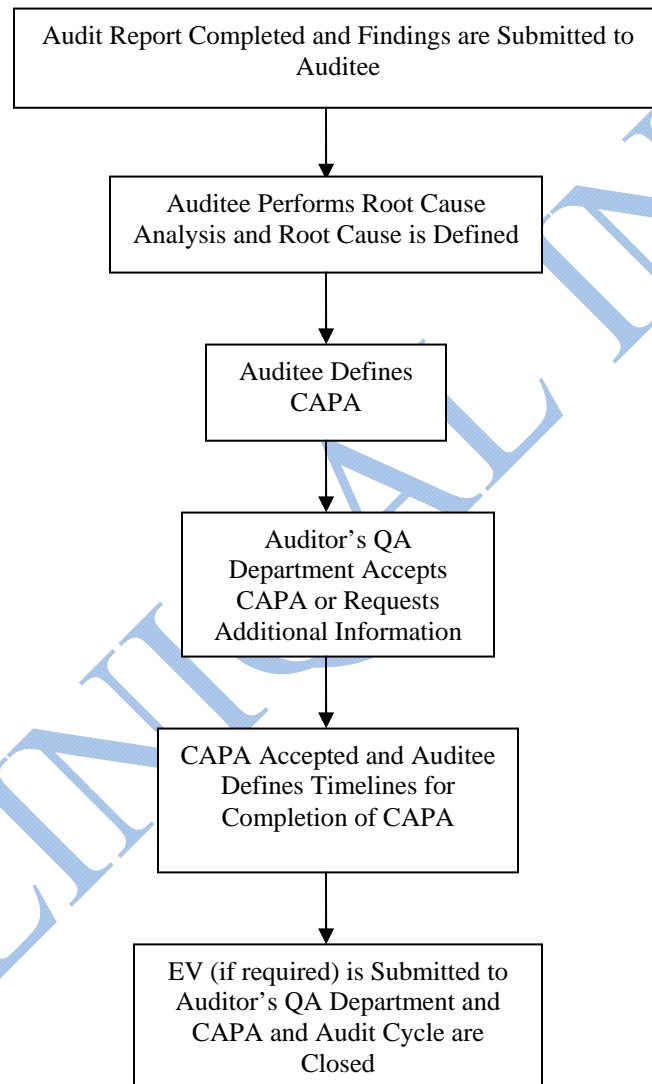


Figure 1 - CAPA Cycle and Audit Closure¹

References:

¹ CLINIQUAL Inc, Guarnacci, Tobin C, www.CLINIQUAL.net

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² Wikipedia on line encyclopedia, http://en.wikipedia.org/wiki/Main_Page

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