



Corrective Action Through Regulatory Eyes

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Objective

- Terminology
- Problem Statements
- Identify Root Cause(s)
- Identify Actions (Plan)
- Verification of Identified Actions
- Implement Actions
- Effectiveness Checks



Corrections

- Action to Eliminate Detected Nonconformity
 - e.g., Rework
- Immediate or Short Term Steps to Control & Mitigate
 - Address immediate risk or safety issue
 - **Stop** problem from getting worse
 - e.g., Containment, Stop Shipment/Supply, Issuance of Advisory Notice



Containment Actions

- Includes:
 - Correction
 - Immediate Corrective Action
 - Immediate Communication
 - Verification that the Nonconforming Situation Does Not Further Degrade



Corrective vs. Preventive

Corrective Action

- Action to Eliminate the Cause(s) of a Detected Nonconformity or Other Undesirable Situation
- Prevent **Recurrence**

Preventive Action

- Action to Eliminate the Cause(s) of a Potential Nonconformity or Other Undesirable Situation
- Prevent **Occurrence**



Misconception

When Using Acronym **“CAPA”**

Incorrectly interpreted to assume that a
Preventive Action is required for every
Corrective Action



Corrective vs. Preventive

“REACTIVE” Sources

- Corrective in nature

“PROACTIVE” Sources

- Preventive in nature

(potential nonconformities of systems,
processes or products)



“Reactive” Data Sources

Corrective Actions

- Customer complaints
- Audit Results (Internal & External)
- Nonconformances
 - Receiving Inspection
 - In-process Inspection
 - Production
 - Final Test/Inspection



Similarities Regardless of Data Source

- Investigation Steps
- Identification of Root Causes
- Actions Needed
- Verification
- Implementation
- Effectiveness Checks



Investigation

Begins with a statement of the
nonconformity expressed as a
Problem Statement



Nonconformance Structure (ISO Requirement)

3 Parts:

1. ***Nonconforming Condition:***

Details the operation or part of the system that has failed

2. ***Requirement:***

Statement of the requirement that was not satisfied (i.e. internal, standard, customer, legal)

3. ***Objective Evidence:***

Identifies in a traceable manner the specific observed instance(s) (record, documents, equipment) of nonconformity



Nonconformance Example

1. *Nonconforming Condition:*

The system to determine the required frequency of internal audits has failed to ensure that the process for scheduling audits is consistent throughout the documented quality management system.

2. *Requirement:*

Clause 8.2.2: The audit criteria, scope, frequency and methods shall be defined.

3. *Objective Evidence:*

The QMS Section "X" requires an internal audit to cover all elements of the standard at least annually. QMS Section "X-X-X" states internal audits will be accomplished within 18 months. These are contradictory statements.



Nonconformance structure (FDA - 483)

OBSERVATION

Corrective and preventive action activities have not been documented, including investigations of causes of nonconformities, the verification or validation of corrective actions, and implementation of corrective and preventive actions.

Specifically,



Nonconformance structure (FDA – Warning Letter)

Failure to establish and maintain procedures for verifying or validating the corrective and preventive action, to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example,



Investigation

- Majority of time spent → gathering data
- Identify, define & further document
- Review and clarify the information provided
- Consider whether systemic or non-systemic issue
- Interview process owners/operators or other parties involved
- Review documents
- Inspect facilities, or the environment of the event



Review Previous Investigations

- Determine if event is a new problem or recurrence of a previous problem (e.g., an ineffective solution was implemented)



Investigation Tools

Rely on Cause and Effect Relationship *Between*
an **Event** & a **Symptom** of that event

- Cause and effect diagrams
- 5 whys
- Pareto Charting
- Fishbone cause and effect diagrams
- Change analysis
- Risk analysis techniques



Example

Problem Statement

Over the past 2 months, there has been an increase number of nonconformances related to suppliers not providing C of Cs with materials.

WHY? WHY? WHY? WHY? WHY?



REASONS WHY

- In the past did not documented nonconformances for missing C of Cs. Just notified supplier to send C of C.
- Inspectors became that C of Cs were required from all suppliers.
- PO changed to add requirement for C of C with every shipment
- New requirement on PO was unclear & some suppliers interpreted that no C of C was required.



Outcome of an Investigation

- Clearly defined problem statement
- What information was gathered, reviewed and/or evaluated
- Results of the reviews/evaluations
- Identification of possible Root Causes
- Possible solutions to address the causes



Root Cause Analysis

Aspects to consider:

- Materials
- Machine / Equipment
- Environment
- Management
- Methods
- Management System
- Measurement, Monitoring & Improvement





Root Causes/Nonconformities

- Failure/malfunction of incoming materials, processes, tools, equipment or facilities in which products are processed, stored or handled
- Inadequate or non-existent procedures and documentation
- Non-compliance with procedures
- Inadequate process control
- Inadequate scheduling
- Lack of training
- Inadequate working conditions
- Inadequate resources (human or material)
- Process variability (inherent)



Corrective Action Planning

Once the root cause(s) has been determined, then identify & document the necessary:

- Containment Actions
- Corrective Actions
- No further action necessary
(Acceptance under concession & continuance of monitoring)



Verification Activities

Ensure that all the elements of the proposed action (documentation, training etc) will satisfy the requirements of the proposed action



CA Implementation

Implement Corrective Action Plan &
Develop Records that demonstrate that:

- Described actions have been taken
(i.e. records, charts, diagrams)
- Defined time scales have been met



Determine Effectiveness

Verification of Effectiveness

- Gather data over a period of time related to the effectiveness of the implemented action
- Confirms that actions taken were effective as to the intended purpose of the action and did not introduce new issues or concerns



CA Implementation

- Verification of Effectiveness has been completed
- Required approvals have been obtained
- The corrective action is efficient in meeting your overall quality objectives and targets.

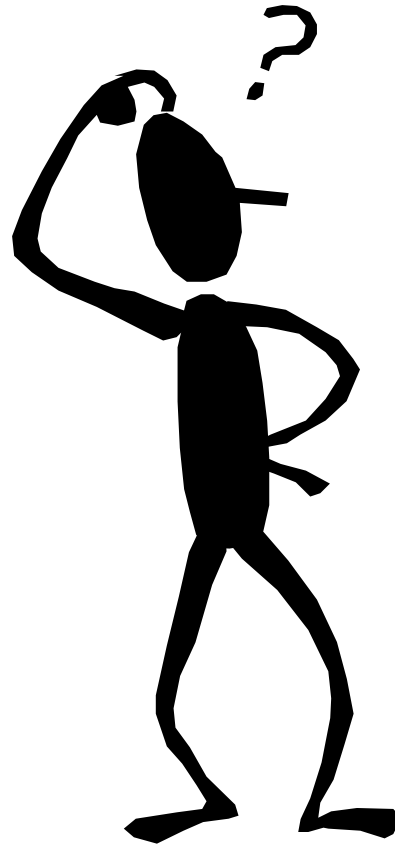


Common reasons for corrective action plan rejection

- Inadequate root cause analysis
- Improper authorization (no signatures, electronic or Scanned, verification signatures)
- Lack of evidence of containment of the issue
- Incomplete corrective action forms (blanks, insufficient data)
- Not all nonconformities have been addressed



Any Questions





Where to Get More Information

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