Corrective and Preventive Actions (CAPA)

Follow Through to Achieve an Effective Quality Management System

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Course Objectives

• Define CAPA

• Describe the seven steps of the CAPA deviation management process

• Describe how a well planned Effectiveness Evaluation can close the deviation management loop.
This presentation has been assembled with the intention of providing valuable information for individuals who are new to the field of Quality Assurance as well as those who have been in the field for a number of years.
WHAT IS CAPA?
CAPA IS...

CAPA (Corrective and Preventive Action) is a deviation management program that focuses on the systematic investigation of discrepancies, adverse events, or failures.
What are the benefits of using CAPA?

If used properly, the CAPA system will provide a means to prevent the deviation from recurring.

How...?

• It provides a structured platform to conduct a systematic investigation of the deviation.

• The investigation provides the means to develop a permanent corrective action.

• It provides a framework for documentation that the corrective actions are indeed effective.
What are the benefits of using CAPA?

Additionally, a CAPA system is the cornerstone of the organization’s Quality Management System (QMS).

21 CFR 1271.160(a) states:

*General.* If you are an establishment that performs any step in the manufacture of HCT/Ps, you must establish and maintain a quality program intended to prevent the introduction, transmission, or spread of communicable diseases through the manufacture and use of HCT/Ps. The quality program must be appropriate for the specific HCT/Ps manufactured and the manufacturing steps performed. The quality program must address all core CGTP requirements listed in §1271.150(b).
CORRECTIVE ACTION

An action taken to eliminate the root cause and symptom of an existing deviation or nonconformity to prevent recurrence.

This is a REACTIVE action that eliminates problems identified in products, services, or processes and takes care of the immediate problem.

The horse has already escaped the barn.
This is an action taken to eliminate the potential causes of a nonconformity, defect, or other undesirable situation in order to prevent occurrence.

This is a PROACTIVE action which avoids deviations through planned activities.

It also eliminates or reduces the recurrence of the problem.
The CAPA System
The Seven Steps of the CAPA Process

1. Discovery of the Deviation
2. Documentation of the Events
3. Immediate Corrective Action
4. Investigation of the Root Cause
5. Causal Analysis
6. Corrective Action
7. Effectiveness Evaluation
Means of Discovery

- External Audits
- Internal Audits
- Staff Observation

- Performing a task
- Inspection or Testing
- Process and Equipment Monitoring
- Record Review

- Change Control
- Material Review Boards

- Complaints
- Adverse Events
- Product Returns or Recalls
- Notification by a customer or a client
Documentation
Documenting the Deviation

The objective is to create a document that is an accurate, complete description of the event so that anyone can understand it.

– External Auditors
– Internal Auditors
– Technical Staff
– Administrative Staff

Essentially, the document should contain all the details needed, without the use of jargon.
To create a well documented and effective narrative avoid the use of subjective, fuzzy, or longwinded statements.

Other documentation considerations:
- If it isn’t documented, it didn’t happen
- If it isn’t documented, it doesn’t exist.
- Precise, economical word usage
Questions to consider

In describing the facts of the deviation, include accurate descriptions of the following details:

- **What** was discovered?
- **Who** was involved?
- **When** did the event occur?
- **Where** did the deviation occur?
- **How** was the deviation discovered?
- **How** frequently does the process occur?
Immediate Corrective Action
Corrective Action Objectives

An Immediate Corrective Action is essentially a description of the steps taken to gain control of a situation or product immediately following the discovery of a deviation.

The immediate corrective action keeps the deviation’s scope from expanding. It also quickly resolves or corrects a discovered event, problem, or situation until the root cause is determined.
Examples of Immediate Corrections

Products
- Quarantined
- Isolated
- Discarded

Equipment
- Removed from Service
- Replaced

Processes
- Manufacturing Suspended
- Test Results Withheld
- Recovery Procedure Halted
Objectives

• Understanding of how or why the deviation occurred.
• Understanding of the circumstances at the time of the deviation
• Determination of other products, processes, or individuals were involved
• Gathering of data to aid in the accurate future determination of a root cause and development of corrective action.
Data Collection

- Interview: Staff, Customers, Suppliers
- Review: Policies, Procedures, Forms
- Record Review:
  - Training
  - Production
  - Equipment
  - Computer
  - Donor Chart
Causal Analysis
Causal Analysis Objectives

- Discover the primary (root) cause
- Result in recurrence prevention
- Reduce operational risks
- Improve operations
- Maintain quality and compliance
RCA Principles

• The conclusions derived from a RCA must be the result of a systematic process which contains well documented evidence.

• Any given problem will have more than one root cause.

• To be effective, the RCA must establish all known causal relationships between the root causes and the defined problem.

• Performance improvement measures directed at root causes are more effective than treating the symptoms of a problem.
A thorough investigation will provide the needed information to establish the root cause.

The following questions are useful in gathering data during a Root Cause Analysis (RCA).

– Who was involved in the deviation?
– What was the deviation?
– Where did the deviation occur?
– When did the deviation occur?
– How did it happen?
– How frequently does it happen?

The questions serve to capture the maximum amount of detail regarding the deviation or occurrence. They help provide data to understand why the deviation occurred.
The Root Cause Analysis is also aided by asking questions that relate to barriers to deviation.

- Describe any physical, organizational, or process barriers in place to detect deviations.
- Were the barriers were in place?
- What was their level of effectiveness?
- Describe any barrier failures.
More RCA Questions

Are there environmental problems?
  Are the work conditions suitable?
  Are there process flow problems?
  Are there facilities problems?

Are there any equipment or materials problems?
  Are instructions for use clear?

Are there problems with staff communication or staff training?
  Is there adequate supervision?

Are there problems with the methods, SOPs, forms, or task analysis?
  Do the steps performed match the operating procedures?
  Has a process recently changed?
Pick a Systematic Technique

Consistent application of one or more of these problem solving tools along with the questions mentioned will provide a good platform to arrive at an accurate determination of root cause or causes.

- 5 Whys
- FMEA
- Pareto Analysis
- Fishbone
- Causal Factor Tree Analysis
- Barrier / Change Analysis
- task analysis
- Observation
Corrective Action
To generate a plan of action that will eliminate or reduce the incidence of the root cause of the deviation, failure, or breakdown.
Consider the following elements when preparing and documenting the corrective action plan:

- Decide the means to implement the action
  - SOPs
  - Process changes
  - Training or Retraining
  - Implementation of automation or new equipment

- Decide on the implementation timeframe
- Determine the method of CA communication
- Determine staff involved in carrying out the CA
Corrective Action Considerations

• Do not expand the corrective action beyond the identified root cause.
• The corrective action must match the root cause of the deviation.
• If possible, build the corrective action upon existing or known barriers.
• Remember that continuous correction is not quality improvement!
Effectiveness Evaluation
Effectiveness Evaluation Objective

The objective of the Effectiveness Evaluation is to generate documentation that proves or disproves the following two statements:

- The Corrective action was completed and implemented as planned
- The corrective action was effective in the reduction or halt of recurring deviations.
Effectiveness Evaluation Steps

- Verify that corrective action was properly implemented
- Determine data source for Effectiveness Evaluation
- Determine when to perform Effectiveness Evaluation
- Determine evaluation period
- Consider impact of learning curve
- Determine success criteria
Who carries this out?

• Operations management is responsible for the planning, completion and reporting of the effectiveness evaluation.
• Reporting of the Effectiveness Evaluation consists of documented evidence of the effectiveness of the corrective actions taken for the event.
In most cases, the evaluation should be started no earlier than 30 days. This ensures that the staff is competent and familiar with the corrective action submitted.

Depending on the organizational SOP, the evaluation for effectiveness should begin within 60 days of the corrective action plan implementation date.

Depending on the organizational SOP, the evaluation should be completed no later than 120 days after corrective action implementation.
Effectiveness Measurement

- Observe staff directly involved in the execution of the corrective action alongside a small sample of other staff members (one to five) not directly involved in the corrective action.

- Review source documents involved in the corrective action for one to three months post implementation. Look for omissions, corrections, or completion attributes that reflect a recurrence of the original deviation.
Effectiveness Measurement

• Staff may be interviewed individually or as a group to ensure understanding of the process in question. Role playing exercises using corrective action scenarios may also be used to ensure understanding.

• Operations or Quality Assurance may perform a post corrective action audit to determine overall effectiveness.
Generate a test or quiz to ensure understanding of the process change initiated for the corrective action. Questions may utilize documents or forms involved in the corrective action or may include written questions that involve analysis of a real life case study.

- Include an example of the test
- Supply a list of employees that have completed, including the date completed
- Operations should generate a memo to document the outcome of the test results
- Do not include the actual tests
Documentation of Results

For each effectiveness evaluation performed, a memo should be generated to document and summarize what was done for the evaluation and the resultant outcome.

Details including the date range, persons performing the operation, and specific root cause being evaluated should be documented in the memo.
In the event of a failed Evaluation

Issue a new deviation or nonconformity.

The Root Cause Analysis will need to be redone.

Items to consider:

- There may have been multiple root causes that were not initially discovered.
- There may have been significant contributing factors that were not discovered.
Summary
To summarize...

- Define the problem.
- Gather data/evidence.
- Ask why and identify the causal relationships associated with the defined problem.
- Identify which causes if removed or changed will prevent recurrence.
- Identify effective solutions that prevent recurrence, are within your control, meet your goals and objectives and do not cause other problems.
- Implement the recommendations.
- Observe the recommended solutions to ensure effectiveness.
THANK YOU

QUESTIONS ??