Corrective and Preventive Actions

“A Five Step Approach”

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Topics to Be Covered

- What is CAPA?
- Governing authority
- Five steps to a good CAPA process
- Where companies have difficulty
- Example citations
- Recap…
What Is CAPA?

- **Corrective Action**
  - eliminate detected nonconformity

- **Preventive Action**
  - prevent nonconformity occurrence
CAPA Process Map

1. Deviations/OOS/Failure
   Problem Occurs

2. Determine Root Cause

3. Determine Corrective Action

4. Initiate CAR
CAPA Process Map

1. CAR Respondent(s) and Approver(s) Determined
2. Respondent(s) Provides Corrective Responses, Root Cause Verification, and Implement Due Dates
3. Response(s) Summarized

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CAPA Process Map

Response(s) Approved

Corrective Action Implementation begins
Respondent(s) review similar systems for Preventive Action Opportunities
Effectiveness review date set

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CAPA Process Map

Respondent(s) sign-off when implementation is complete

Effectiveness is reviewed and signed-off

CAR Closed
Subpart J – Records and Reports

211.192 “Any unexplained discrepancy shall be thoroughly investigated. The investigation shall extend to other batches ...that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include conclusions and follow-up.”
6.5 - Batch Production Records

6.53 - “Written procedures should be established for investigating critical deviations or batch failures of intermediate or API to meet specifications. Investigations should extend to other batches.”
Subpart J - Corrective and Preventive Action

(a) Manufacturer shall establish procedures for implementing corrective and preventive action. The procedures shall include requirements for:
Subpart J – CAPA cont.

(1) “Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product” …“identify existing and potential causes of nonconforming product, or other quality problems”…”statistical methodology shall be employed to detect recurring quality problems”
Subpart J - Corrective and Preventive Action

(2) “Investigating the cause of nonconformities relating to product, processes, and the quality system;”
“Identify action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;”

(4) Verifying or validating the corrective and preventive action to ensure actions are effective;”

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Subpart J - Corrective and Preventive Action

(5) “Implement and record changes in methods and procedures needed to correct and prevent identified quality problems;
Subpart J - Corrective and Preventive Action

(7) Submitting relevant information on corrective and preventive actions, for management review.
Five Step Approach

- Identify
- Implement
- Review
- Verify
- Analyze

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Where Companies Have Difficulty

Identify
Implement
Review
Verify
Analyze
Identify: Problem but not root cause

Implement: CA wrong

Review: PA does not work

Verify: Problem recurrence

Analyze: Not done

Incorrect Root Cause Identified!

Why?
CAPA Subsystems

- MRB
- OOS
- COMPLAINTS
- VALIDATION
- MANAGEMENT REVIEW
- TRENDING
- TRAINING
- AUDITS
- CHANGE CONTROL
- RECALL
- APR
- DEVIATIONS

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Example Citations
Example Citations - CDER

Failure to implement corrective/preventive action or conduct a thorough investigation
– 21 CFR 211.192
– 21 CFR 820.100

Examples
  Repeated test failures not investigated
  Inadequate investigation of failed particulate inspection
Example Citation – CDER – Q7A

• “Failure to document corrective action regarding instrument calibration check which did not meet specification”
Example Citation - CBER

• Failure to establish and maintain adequate procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a) and (b). For-example:

• (a) The procedure titled corrective Action Handling [redacted] was not approved and implemented to address corrective and preventive action and no established procedure was found to have been in place.
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Example Citation - CDRH

“Failure to adequately establish and maintain procedures for implementing corrective and preventive actions as required by 21 CFR 820.100(a)(1)”

Example: a. “Corrective Action Request # & # were not closed out by the QC Supervisor as required by (SOP) Corrective and Preventive Action, Rev 1; and
Identify
Implement
Review
Verify
Analyze
“Failure to adequately establish and maintain procedures for implementing corrective and preventive actions as required by 21 CFR 820.100(a)(1)”

Example : (b) (SOP) Corrective and Preventive Action, identifies repair reports as a source for identification of potential CAPA activities; however, repair reports are not being trended or reviewed for CAPA

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Analyze
Verify
Review
Implement
Identify
RECAP
Recap

LACK OF ROOT CAUSE ANALYSIS

Identify
Implement
Review
Verify
Analyze
CAPA Subsystems

- COMPLAINTS
- MANAGEMENT REVIEW
- TRAINING
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- APR
- DEVIATIONS
- MRB
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Questions?

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