Writing CAPAs to Reflect Your Compliance Initiatives

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Agenda

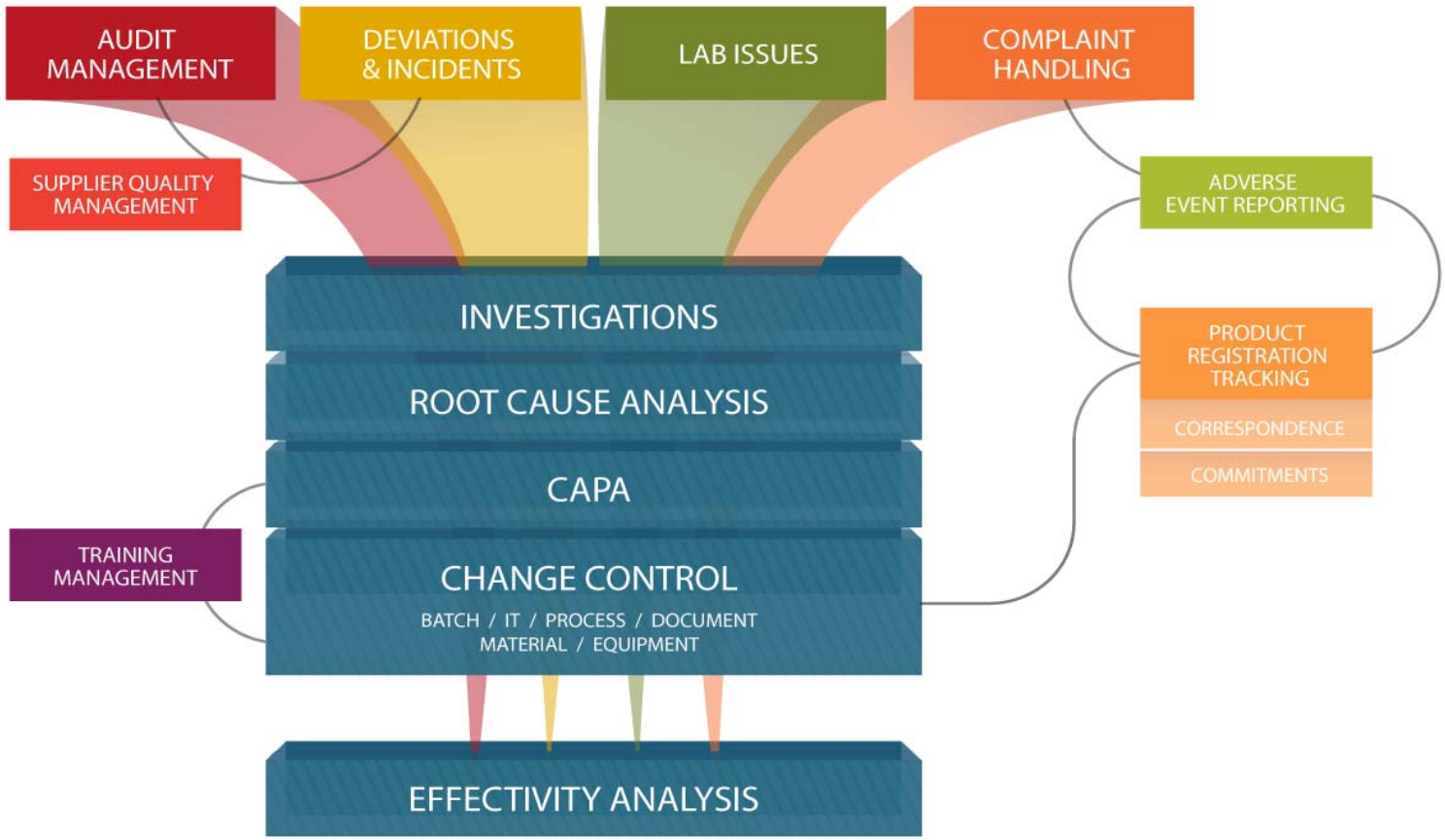
- Common CAPA Challenges
- Delegating Responsibility and Authority
- Determining Whether to Open CAPA
- Applying the Definitions
- Establishing Criteria and Applying the Criteria When it Doesn’t Exactly Fit
- Evaluating CAPA Documentation

Common CAPA Challenges

- Documentation takes place at the end of the process, thereby failing to tell full story of steps taken along the way
- Inconsistency in applying definitions and process, especially in large organizations
- Evolves into task-management catch-all, rather than business tool to focus resources on highest-risk items

Most common CAPA challenge

Rather than this:



Delegating Responsibility and Authority

BENCHMARKING EXERCISE

Concept

- While nonconformities need to be corrected, not all nonconformities become CAPAs. The goal here is to discuss the pros and cons of various systems to determine who makes the decision of when a nonconformity becomes a CAPA.

Exercise 1: Page 2 in the Workbook.

- You work for the Red Company and you are designing your CAPA system. You know that some firms allow anyone to open a CAPA, and other firms require that the person who wants to open a CAPA write a request that will be submitted to a management council.
  1. List the pros and cons of allowing anyone to open a CAPA (no more than three).
  2. List the pros and cons of requiring people to submit a request to the management council to open a CAPA (no more than three).
  3. State which would be the best practice for the Red Company and explain why

Determining Whether to Open CAPA

BENCHMARKING EXERCISE

CAPAs and Risk

- CAPAs are based on risk, taking into account the frequency with which the nonconformity might occur and the severity of the risk if the nonconformity did occur.

Quality System Preamble

Comment 165 states: "... [T]he objective of 820.100 is to correct and prevent poor practices, not simply bad product. Correction and prevention of unacceptable quality system practices should result in fewer nonconformities related to product… For example, it should identify and correct improper personnel training, the failure to follow procedures, and inadequate procedures among other things."

Exercise 2: Page 3 in the Workbook

- When Mike Bates, the manager of training, reviewed the training records, he noted that the trainer failed to include the date that the training was conducted. For each situation below, determine whether the incident needs a correction or needs to be elevated to a CAPA.
  - Incident happened on Feb. 2, 2010 by Tim Jones.
  - Incident happened on Feb. 2, 2010, Feb. 11, 2010, and March 1, 2010 by Tim Jones.
  - Incident happened on Feb 2, 2010 by Tim Jones, Feb. 11, 2010 by Susan Smith, and March 1, 2010 by Carol Sacks.
  - Incident happened 15 times when different people were the trainers between Jan. and June 2010.

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DEFINITIONS

Definition: Correction

"Correction" - action to eliminate a detected nonconformity.

1. A correction can be made in conjunction with a corrective action.
2. A correction can be for example, rework or regrade.

ISO 9000:2005(E)

Definition: Corrective Action

"Corrective action" - action to eliminate the cause of a detected non-conformity or other undesirable situation."

1. There can be more than one cause for a nonconformity.
2. Corrective action is taken to prevent **re**currence.
3. There is a difference between correction and corrective action.

ISO 9000:2005(E)

Definition: Preventive Action

"Preventive action" - action to eliminate the cause of a potential non-conformity or other undesirable situation.

1. There can be more than one cause for a potential nonconformity.
2. Preventive action is taken to prevent **oc**currence

ISO 9000:2005(E)

Applying the Definitions

BENCHMARKING EXERCISE

Exercise 3: Page 4 in the Workbook

- Directions: Choose the best response and be prepared to defend your answer.
  - To evaluate the effectiveness of 1) how a firm dealt with the failure of trainers to list the date on a training record and 2) how the firm will avoid that exact same nonconformity in the future, the investigator should ask for the firm's:
    a. Correction, correction action and preventive action
    b. Correction and correction action
    c. Corrective action

Establishing Criteria and Applying the Criteria When it Doesn't Exactly Fit

BENCHMARKING EXERCISE

Concepts

- Companies need to establish criteria to justify that the nonconformity can by fixed by a correction rather than a CAPA.
- High risk is easy.
- Low risk must be rationalized:
  - How do you establish that number?
  - How do you know you have all of the necessary data?
  - What retrospective analysis will you be doing?

Exercise 4: Page 5 in the Workbook

- You are writing an SOP or guidance on your threshold for instituting a CAPA.
  1. List 3 criteria that you might use.
  2. How do you address instances where you don't have all of the data needed to support your conclusion? (For example, the criteria says you will initiate a CAPA if an event occurs more than 4 times in a year. You have only been making the product for 2 months and you have 2 occurrences.)

Writing CAPA Documents

- Purpose of CAPA documentation is to provide:
  - A structure for directing current and future activities
  - A tool for forward and backward traceability
  - The history explaining how the company complied with the requirements to
    - Correct the nonconformity
    - Based on a risk assessment, employed reasonable measures to limit the risk of its customers from being exposed to unsafe or ineffective products.

OM 5.3.6.2 - Inspection Techniques How to Document Responsibility

- In order to establish relationships between violative conditions and responsible individuals, the following types of information, would be useful:
- Who knew of conditions?
- Who should have known of the conditions because of their specific or overall duties and positions?
- Who had the duty and power to prevent or detect the conditions, or to see they were prevented or detected?
- Who had the duty and power to correct the conditions, or to see they were corrected? What was done after person(s) learned of the conditions? Upon whose authority and instructions (be specific)?

OM 5.3.6.2 - Inspection Techniques How to Document Responsibility

- What orders were issued (When, by whom, to whom, on whose authority and instructions)?
- What follow-up was done to see if orders were carried out (when; by whom; on whose authority and instructions)?
- Who decided corrections were or were not complete and satisfactory?
- What funding, new equipment, new procedures were requested, authorized or denied in relation to the conditions; who made the requests, authorizations, or denials.

For Precise Writing

- Don’t use the passive voice
- Characteristics of the passive voice
    - A form of the verb “to be” is combined with the past participle of another verb.
        - Were conducted
        - Has been distributed
        - Were closed

Passive Voice

- Many times the writer doesn't disclose the actor or other details that a person reading the document would need in order to find out what actually happened.
  - The audits were conducted
  - The report has been distributed
  - The complaints were closed

The Active Voice

- The subject generally precedes the verb
- The verb denotes action not existence
- The writer is encouraged to be specific
  - Sue Smith, senior auditor, conducted the audit on June 15, 2010.
  - On January 12, 2010, Larry Tote, vice president of quality, distributed the 2009 Annual Quality Report to members of Tote's Quality Council.
  - Harry Hamlin, Tote's complaint coordinator, closed complaints 1342, 1343 and 1345 on March 2, 2010.

Patient Lift

- Chronology
- Product marketed for use in nursing homes in June 2009
- Labeling stated don't use on people who weigh more than 150 lbs.
- August 2009, lifts in 4 nursing homes broke because of nut bolt connection
- Nursing home representative stated that in 2 cases, people using the lifts weighed more than 150lbs.
- In the other cases, nursing home staff said they complied with the user instructions.

Evaluating CAPA Documentation

BENCHMARKING EXERCISE

Exercise 5: Pages 6-7

- Take a few minutes and evaluate the usefulness of the CAPA documentation.

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QUESTIONS AND ANSWERS