

HOW TO WRITE CAPAs TO REFLECT YOUR COMPLIANCE INITIATIVES

EXERCISES

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Writing CAPAs to Reflect Your Compliance Initiatives

Exercise 1

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. Explain which would be the best practice for the Red Company and explain why

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Exercise 2

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.

1. Incident happened on Feb. 2, 2010 by Tim Jones.

2. Incident happened on Feb. 2, 2010, Feb. 11, 2010 and March 1, 2010 by Tim Jones.

3. Incident happened on Feb 2, 2010 by Tim Jones, Feb. 11, 2010, by Susan Smith, and March 1, 2010 by Carol Sacks.

4. Incident happened to 15 times when different people were the trainers between Jan. and June 2010.

Exercise 3

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

Exercise 4

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.)

Exercise 5

Directions: Evaluate the CAPA report below.

a. Identify the issue

- In four different nursing homes, the nut bolt connection on patient lift number 3475 Y failed causing the lift to fall apart.

b. Identify root cause

- The nut and bolt were made of zinc plated steel and this material was not adequate

c. Identify actions to correct and prevent recurrence

- By October 1, 2009, the R&D Department will reengineer the design by testing different materials for desired performance
- Within 30 days of receiving the new design, the XX department will test it and determine if it can be applied to units in the field.
- Within 14 days of receiving the positive test results, the XXX Department will follow the SPO # 2837 and do a design change to implement.
- Within 7 days of receiving the paperwork on the design change, the Regulatory Department will update documents, validate, and notify regulatory bodies as

d. Verify or validate effectiveness

- Before launch
- The R&D Department will test 150 units with a 200 pound weight to determine if the lift can meet the requirements stated in its labeling.
- The R&D Department will perform accelerated use test to simulate the stress for 10 years of use
- Validation testing (Retrospectively)
- After 3 months of the product being in the field, the Quality Department will review customer complaints to determine if there are any instances of a failure of the nut bolt connection.

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- At the same time, the Quality Department will examine all complaints related to the 3745Y lift to see if there are any new issues that relate to the change.
- appropriate.

e. Implement and record the changes in methods and procedures

- When XX is completed, the Quality Department will update SOP 2830 and 3099
- The Purchasing Department will modify the purchasing specifications in XXX

f. Disseminate the information to the appropriate people

- When XXX is complete,
 - The Operations Department will send a memo to shop floor supervisor who will conduct training on the new procedure
 - The Director of Sales will send a memo to sales people and schedule a call to explain the change.
 - The Service Director will send a memo to the repair people and have a call to explain the change.