CAPA Issues and Pitfalls

Timothy Barash, BSI

April 3, 2014

CAPA: Corrective Action, Preventive Action

It does NOT mean JUST Corrective Action!

A CAPA Story

Overview

- A CAPA Story
- Core CAPA Steps
- CAPA Standards
- Issues
  - Containment
  - Root Cause Analysis
  - Action Plan Implementation
  - Verification of Effectiveness
  - Preventive Action

Core CAPA Steps

- Nonconforming Condition or Potential Nonconforming Condition
- Containment
- Root Cause Analysis
- Action Plan
- Action Plan Implementation
- Verification of Effectiveness

CAPA Standards

Eight Disciplines Problem Solving (8D)

- D0: **Plan**:
- D1: **Use a Team**:
- D2: **Define and describe the Problem**:
- D3: **Develop Interim Containment Plan; Implement and verify Interim Actions**
- D4: **Determine, Identify, and Verify Root Causes and Escape Points**
- D5: **Choose and Verify Permanent Corrections (PCs) for Problem/Non Conformity**
- D6: **Implement and Validate Corrective Actions**
- D7: **Take Preventive Measures**:
- D8: **Congratulate Your Team**

CAPA Standards

ISO 9001:2008

8.5.2 Corrective action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken, and

f) reviewing the effectiveness of the corrective action taken.

CAPA Standards

ISO 13485:2003

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed, including, if appropriate, updating documentation,

e) recording of the results of any investigation and of action taken, and

f) reviewing the corrective action taken and its effectiveness.

CAPA Standards

FDA Quality System Regulation (21 CFR Part 820)

Sec. 820.100 Corrective and preventive action

- (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:
- (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
- (2) Investigating the cause of nonconformities relating to product, processes, and the quality system;
- (3) Identifying the 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 that such action is effective and does not adversely affect the finished device;
- (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
- (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
- (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.
- (b) All activities required under this section, and their results, shall be documented.

CAPA Issues

- Nonconforming Condition or Potential Nonconforming Condition
- Containment
- Root Cause Analysis
- Action Plan
- Action Plan Implementation
- Verification of Effectiveness

CAPA Issues

Containment

- No consideration of Containment

(An analysis of containment is a BSI Requirement)

CAPA Issues

Root Cause Analysis

- Restatement of the problem
- Insufficient depth of analysis (no “5-Whys”, etc.)
- No analysis of the breadth of the nonconforming condition (isolated event versus systemic problem)

CAPA Issues

Action Plan Implementation

- Action plan not fully implemented with no explanation/reason documented
- Different action plan implemented with no explanation/reason documented

CAPA Issues

Verification of Effectiveness

- Effectiveness = implementation (not!)
- Effectiveness verification inadequate
- Effectiveness verification indicated as “N/A” with no explanation
- Effectiveness verification not conducted
- Not enough time allowed between action plan implementation and effectiveness verification

CAPA Issues

Preventive Action

- Preventive action is NOT a follow-on to corrective action
- No stand-alone preventive actions – preventive actions are required by ISO:

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems……..

CAPA Issues

Preventive Action

- Description of the potential nonconformity is actually a description of the action to be taken
  - Putting the “cart before the horse”
  - What is the “potential nonconformity”?
- No root cause
- No verification of effectiveness

CAPA Issues

Corrective Action V.S. Preventive Action

- Corrective Action - Nonconformity
- Preventive Action - Potential Nonconformity

- Corrective Action – Reactive
- Preventive Action - Proactive


Thank
You!