CAPA – Common Pitfalls

Presented by:

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Topics

- CAPA Process Flow
- Elements of an Effective CAPA System
- Common Pitfalls
CAPA Process Flow
CAPA Inputs

- Complaints & MDRs
- Management Review
- Audits
- Returned Product
- Process Monitoring
- Service
- Nonconforming Product
- Supplier Performance
- Inspection

Threshold not met? CAPA already exists? Isolated event? Collect more data?

Can be resolved through:
- Correction
- Containment
- Remediation

EVALUATION

Initiate CAPA Process

YES

NO
Define the Problem

- Define Problem Statement
  - Assess Risk
- Investigate Cause
  - Re-assess Risk
- Propose Solution
- Verify/Validate

Define the Problem

- Focus on facts
- Avoid emotions
- What, Where, When, How, Much

Assess Risk

- Customer, Employee, Regulatory, Business
Investigate Cause

- Contain nonconformity
  - Investigate to the level necessary based on significance and risk to:
    - Determine probable cause
    - Determine scope of the problem

- Re-assess risk

- Cause unknown?
  - ...what action IS necessary

- Initiate CAPA
- Define Problem Statement: Assess Risk
- Investigate Cause: Re-assess Risk
- Propose Solution
- Verify/Validate
Propose Solution

Initiate CAPA

Define Problem Statement
Assess Risk

Investigate Cause
Re-assess Risk

Propose Solution

Verify/Validate

Multiple Causes
- Probable cause, contributing cause
- Prioritize based on risk

Document rationale for
- choosing one solution over another or no corrective and preventive action

Confirm solution will not have an adverse effect on the product
Verification / Validation

- Investigate Cause
  - Re-assess Risk

- Propose Solution

- Verify/Validate

  - YES
    - Implement

  - NO

Verify or validate *before* implementation

- Will planned actions have an adverse effect on the product?
- Will solution eliminate cause?

What is the impact on product, process or quality system?
Action Plan

Implement Action Plan

Action Plan Complete

Effectiveness Check

YES

Close CAPA

Appropriate, timely and effective
• who, what, when, deliverables

Implement and record changes in methods and procedures
• change control 820.30, 820.40, 820.70

Action Plan Complete
Effectiveness Check

Plan

Define method
• Select data source to monitor for early detection
• Audit

Establish timeframe

Close CAPA if results are acceptable
CAPA – two step closure

1. Complete
   Action plan implemented, pending effectiveness check

2. Close
   Effectiveness check successful
Elements of an Effective CAPA Process
Elements of an Effective CAPA Process

- Documented procedure(s)
- Defined inputs
- Method to assess risk and prioritize problems
- Containment
- Investigation disciplines
- Method to assess risk and prioritize solutions
- Verification and/or validation
- Impact assessment
- Well defined action plan
- Disseminate information
- Metrics - ability to monitor progress
- Effectiveness checks (Complete? Effective? Timely)
- Defined criteria for Management Review
- Documentation rules
- Management escalation
Management Escalation

• A means of alerting management with executive responsibility during any phase of the CAPA process
  – Risk
  – Resources
  – Timeliness
    • Investigation, Implementation, Effectiveness Checks
Challenges & Common Pitfalls
Common Challenges

1. Recognizing links to other quality system elements
2. CAPA documentation
3. Resources
4. Process Complexity
5. When to Initiate CAPA
   - Action Limits
   - Speeding Tickets
6. Problem definition
7. Investigating Cause
8. Ineffective follow up
9. Timeliness
   • Aging CAPAS
10. CAPA process automation
11. Inconsistency across Global companies
1. Links to CAPA

CAPA links to all other quality system processes

- Design Controls
- Production & Process Controls
- Management Controls
- Purchasing Controls
- Returned Goods
- Acceptance Activities
- Nonconforming Product
- Complaint Handling
- Installation
- Servicing

... and more
Links to CAPA

- Management Controls
- Production & Process Controls
- Equipment & Facility Controls
- Records, Documents, & Change Controls
- Material Controls
- Design Controls
2. Documentation

• CAPA documentation does not reflect current status

• Level of documentation is not commensurate with the work performed
  – Investigation completed
  – Documentation changes complete or underway
  – CAPA file lacks documented evidence of work performed
  – Documentation rules: forward and backward traceability

• Extensions
  – Are they defensible?
Documentation – *best practices*

- Well defined problem statement
- Correction or containment measures
- Data reviewed (data sources, records)
- Investigation defined
  - method
  - dates of investigation
  - objective evidence
- Results of investigation include statement of cause
- Action plan
  - who, what, when, deliverable
- Forward – backward traceability
- **CAPA file is maintained to reflect current activity level**
3. Resources

- More work - fewer resources
  - CAPA is “Quality” … *let them do it*
- CAPA often competes for resources
  - Complaint Investigation
  - New Product Development
  - Manufacturing Improvements
- Conflicting priorities, changing priorities
- Avoid competing for the same resources by aligning CAPA with quality and business objectives
4. Complex CAPA Process

- Complexity impedes ability to act appropriately
  - Multiple approvals
  - Unnecessary signature requirements
  - Software tool is driving the process
  - CAPA Committees
    - Are participants prepared?
    - Are meetings effective?
Complex CAPA Process (cont.)

• A complex CAPA system contributes to aging CAPAs

• Risk unknown
  – CAPAs enter the system carrying the same weight
  – Sense of urgency is not conveyed
5. Action Limits

- “Speeding Ticket” syndrome
- Perception that
  ... all nonconformities require CAPA
- Alignment with Quality Policy, Quality Objectives and Business Objectives often lacking
Action Limits

• Identify CAPA data sources (product, process, and quality system)

• Define criteria (action limits) for CAPA
  – Consider frequency and severity across multiple data sources
  – Define a risk based approach for prioritization
    • patient/user safety, business, regulatory, employee
  – Leverage the output of Design Control to drive CAPA
    • Risk Analysis: Design FMEA, Process FMEA
6. Problem Definition

- Often ambiguous and subjective
- The problem statement is the difference between what *is* and what *should be*
  - Focus on
    - facts – *not emotions*
    - *what* is wrong, not *why* it’s wrong
- A clear Problem Statement will establish investigation boundaries … *avoid “scope creep”*
Problem Definition (cont.)

• State the problem in measurable terms
  – What, how often, how much, when, and where

• Emphasize the effects of the problem
  – safety, death, injury, rework, cost, etc.

• Avoid
  – inflammatory statements
  – words that are broad and do not describe the conditions or behavior such as careless, complacency, neglect, oversight
7. Investigating Cause

- Costly implementation of a solution that does not address the cause of the problem

- Implementing a solution that addresses the symptom... not the cause

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Investigating Cause (cont.)

• Ultimate goal - determine WHY the problem occurred

• Phases of Investigation
  – Presumptive Cause
    • apparent during early investigation, hypotheses that may explain the effect but needs validation
  – Contributing Cause
    • secondary and possible causes
  – Root Cause
    • primary reason for the problem which if corrected will prevent recurrence
Documenting the Investigation

- **Define method of investigation**
  - Include quality tools used
    - Is/Is Not,
    - Cause and Effect,
    - 5 Why’s, etc.

- **Document**
  - Dates of investigation
  - Data reviewed (data sources, records, dates)
  - Corrections or Containment measures
  - Results: Statement of Cause

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<thead>
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<th>IS</th>
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<tr>
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Is / Is Not Diagram
8. Ineffective Follow-Up

• Effectiveness Checks fail when
  – They are not planned specific to the CAPA
  – An inappropriate data source is selected to monitor for recurrence/occurrence
  – The same criteria is applied to all CAPAs

• What to do when a effectiveness check fails, and what are the consequences?
  – Close the CAPA and open a new one?
  – Get an extension?
  – Leave the CAPA open and investigate why?
Was the Problem Statement well defined?

Data Source indicates problem still exists.
Determine Additional Action

Investigate \textit{Cause} \\
\textit{Re-assess Risk}

Proposed Solution

Verify/Validate

Implement

Action Plan Complete

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9. Timeliness and Metrics

Not all CAPAs are created equal

- Major
- Moderate
- Minor

- Aging Investigations
- Failed Effectiveness Checks
- Overdue Effectiveness Checks
- Implementation Overdue
10. CAPA Software

- AUTOMATION is a TOOL …not a solution

- Define your CAPA process *first*, then automate
- Walk before you run
- Recognize the CAPA process is fundamental
11. Global Companies

• Global companies must overcome perceptions
  – Our businesses are different
  – Our methods are different
  – Our terminology is different
  – Our cultures are different
  – A sense that each
    • product,
    • process, or
    • quality system
    …is unique
Global Companies (cont.)

• CAPA processes should be same/similar to meet regulatory obligations and business objectives

• WHY?
  It makes good business sense to leverage success!
Global Companies (cont.)

- Opportunities exist to consider similar issues across multiple facilities
  - Share product, process and quality system information from various locations, sister facilities, manufacturing plants, to emphasize both problems and solutions
  - Act on information
In Closing ...
“The significant problems we face can not be solved at the same level of thinking we were at when we created them”

Albert Einstein
Thank-You!

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