The Importance of CAPA and Root Cause Analysis for the Food Industry

Dr. Bob Strong
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SAI Global Assurance Services, Training & Improvement Solutions
Our Presenter Today

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• Driving force behind our food safety operations in the areas of Good Manufacturing Practice (GMP), Good Agricultural Practice (GAP) and supplier assurance programs, including SAFE, SQF and BRC

• 44 years of experience in the food industry, while working for national and international companies in quality assurance, product development and auditing. He is an often requested seminar speaker in the areas of GMP and HACCP

• Ph.D. and BSC in Chemistry and an accomplished food safety trainer for numerous food safety manager certification courses

• In addition, he is a GMP/HACCP instructor, a Lead Auditor trainer, and is also certified to consult on the Global Food Safety Initiative by SQF. He is certified in 20 product categories
Agenda

- Definitions
- Deming Wheel
- CAPA Process
- Root Cause Analysis (RCA)
- 5 Why approach to problem solving
- Fishbone method of resolving problems
- Benefits of CAPA and RCA
Terminology

- Nonconformity
- Correction (Immediate Action)
- Corrective Action (CA)
- Preventive/Preventative Action (PA)
- Root Cause (RC)
- Root Cause Analysis (RCA)
Nonconformity

Refers to the failure to comply with a requirement of a program and/or failure to perform a required task.

These nonconformities can be:

- Critical
- Major
- Minor
- OIP
Difference Between

- Corrections
- Corrective Actions
- Preventive Actions
Corrections

- These are immediate actions taken to eliminate a detected nonconformity.

- These actions need to be completed as soon after detecting the nonconformity as possible.

- These Corrections allow you to continue your operations but this correction should only be allowed if there is no food safety threat to the consumer.
Corrective Action

- Corrective Action is an action taken to eliminate the cause of the detected nonconformity or other undesirable situation.

- This requires determination of the Root Cause in order to ensure the action taken will be effective and prevent recurrence.
Preventive (Preventative) Action

- Preventive Action is a step taken to remove the causes of a potential nonconformity or potential situation that is undesirable.

- The preventive action is therefore designed to prevent the occurrence of nonconformities or situations that do not currently exist.

- It therefore strives to prevent occurrence by eliminating causes.
What is the difference between the words *preventive* and *preventative*?

– Leah, United States Webster’s Dictionary

- There is virtually no difference between *preventive* and *preventative*.

- Both words are adjectives that mean, "used to stop something bad from happening."
Care needs to be taken at this preventive action step

- Quite often we grasp the first solution and run with it.
- We do not continue our investigation because it takes time we feel we do not have, or we are not willing to give.
- We are looking for the “easy answer” to correcting our nonconformities.
- We treat the symptoms not the cause.

HENCE

- The problem worsens or the problem comes back

NEXT STEP ➔ ROOT CAUSE ANALYSIS
What is a Root Cause?

“A root cause is the single, verified reason why a problem occurs.

Once it’s eliminated from the process or system, the problem is completely eliminated.”

➢ Care has to be taken to always treat the cause and not the symptom.
Root Cause Analysis

Root Cause Analysis is a method of problem solving that seeks to identify the essence of issues that cause negative operating events.

It is a systematic approach to identify the root cause of a problem:

- 5 Whys;
- Cause and Effect (Fishbone Diagram);
- Other methods are available.
How to perform Root Cause Analysis
Individual vs. Team Approach to Problem Solving

Depends on nature of problem but multiple heads are better than one.

Benefits of team approach

- Variety of perspectives
- Variety of skills
- Synergy
Consensus Decision Making

Results in an agreement of the team’s thinking as a whole
Involves discussion and examination of each others’ opinions
Generally produces the most effective corrective actions
CAPA Process

1. **Identify** – clearly define the problem.
2. **Evaluate/review** – appraise the magnitude and impact.
3. **Investigate** – plan to research the problem.
4. **Analyze** – for the root cause.
6. **Implement** – execute the action plan.
CAPA Process

1. **Identify** – clearly define the problem
How to Perform Root Cause Analysis

1. Identify All Possible Causes
2. Narrow the List of Possible Causes
3. Verify the Root Cause
Describe the Problem

- **Who?** – Individuals/customers associated with problem
- **What?** – The problem statement or definition
- **When?** – Date and time problem was identified
- **Where?** – Location of complaints (area, facilities, customers)
- **Why?** – Any previously known explanations
- **How?** – How did the problem occur? Under what circumstances?
- **How Many?** – Size and frequency of problem
Describe the Problem

“**It Is**” and “**It Is Not**” Analysis

- Sharpens the definition of the issue/ the scope
- Helps so you don’t look down some wrong paths
- Document what you determine
- Use this data in the next steps
When the problem is known the next question begins the “5 Why” process

The question needs to be:
- Short
- Simple
- Concise
- Focused on one problem
- Is a question starting with Why.........?

The question does not:
- Tell what caused the event
- State what to do next
- Explain the event
Using the “5 Whys” to Investigate Causes

Ask “why” until reaching the root cause
Analysis

This process uses the Why - Why - etc. method to build a cause chain because it is a natural, logical progression for thinking through a problem.

The 5-Why process is called that because, generally speaking, it takes 5 “whys” to get to the logical end of the cause chain.
Problem: Surface defects appear on door panels after prime spray operation

Why do surface defects appear on door panels?
Prime spray is contaminated

Why is the prime spray contaminated?
Loose, crumbly paint falls off overspray booth

Why does paint fall off overspray booth?
Booth is not properly maintained

Why is the booth not properly maintained?
Maintenance personnel are not properly trained

Why aren’t they properly trained?
No documented procedures for cleaning booth
**Problem:** Personnel door is a potential pest issue

- **Why** is the door a potential pest problem?  
  Needs weather-stripping at bottom

- **Why** is the weather strip getting damaged?  
  Because door is warped

- **Why** is the door getting warped?  
  Because employees prop door open

- **Why** do employees prop doors open?  
  To go out to smoke

- **Why** do they do go out this door?  
  Because they can
The Importance of Root Cause Analysis

Unless you identify a problem’s root cause, you cannot resolve it.

- Ask:
  - What went wrong?
  - How was the problem missed?
  - What changed?

- Use idea generating techniques to identify possible root causes
- Use a decision-making technique to select a cause to investigate further
Fish Bone Approach

Process
(where problem occurred)

- Man (person)
- Material
- Environment

- Machine
- Method
Fishbone Diagram: The Cause and Effect Diagram

Categories using terms that make sense in your companies:

- Method = Procedures = Practice = Know-how
- Equipment = Tools = Proper Use
- Manpower = People = Humans = Workers
- Material = Purchased Product = Correct Type
- Environment = Sanitation = Cleanliness
- Measurement = Gauging = Metrics = Accounting
Fishbone Diagram

The Cause and Effect Diagram

- Once the branches are labeled, begin brainstorming possible causes and attach them to the appropriate branches.
- For each cause identified, continue to ask “why” does that happen and attach that information as another bone of the category branch.
- Prioritize the key causes identified on the fishbone.
- Once you have the fishbone completed, you will see the picture of possible root causes of the problem.
Questions to Ask: People

- Does the person know what he is expected to do in his job?
- Is the person trained?
- How much experience does the person have?
- Does the person have the tools/equipment needed to do the job?
- Is the workload reasonable?
- Does the person have adequate supervision and support?
- Do physical conditions such as light or temperature affect their work?
- Who does the person contact when problems arise?
Questions to Ask: Method

- How is the process used defined?
- Is the process regularly reviewed for adequacy?
- Is the process used affected by external factors?
- Have any changes been made recently in the process?
- What adjustments must the operator make during the process?
- How does the operator know if the process is operating effectively?
- Have other methods or processes been considered?
Questions to ask: Equipment

- How old is the equipment or machinery?
- Is preventive maintenance performed regularly on it?
- Is the machine affected by heat or vibration or other physical factors?
- How does the operator know if the machine is operating correctly?
- What adjustments must the operator make during the process?
- Have any changes been made recently in the equipment?
- How is the equipment cleaned?
- What tools are used to clean the equipment?
Questions to Ask: Raw Materials

- What is the source of the raw material?
- Has there been a change in suppliers recently?
- How is the raw material produced?
- How is the safety of the raw material verified?
- How old is the raw material?
- How is safety assessed prior to your operation?
- What is the level of safety and quality?
- How is the raw material packaged?
- Can temperature, light or humidity affect the material quality?
Questions to Ask: Environment

- How are environmental conditions monitored?
- How are environmental conditions controlled?
- How is the environment control measuring equipment calibrated?
- Are there changes in conditions at different times of the day?
- Does environmental change impact the processes being used?
- Does environmental change impact the materials being used?
Questions to Ask: Inspection System

- How frequently are products inspected?
- How is the measuring equipment calibrated?
- Are all products measured using the same tools or equipment?
- How are inspection results recorded?
- Do inspectors follow the same procedures? (Is there a set of standards?)
- Do inspectors know how to use the test equipment?
How to Perform Root Cause Analysis

1. Identify All Possible Causes
2. Narrow the List of Possible Causes
3. Verify the Root Cause
All of these individual steps involve a Corrective Action for a symptom, it is only when you get to the

**Root Cause**

that you are able to address the cause and apply a

**Preventive Action**

to eliminate the problem permanently.
Factors to Consider Before Doing Corrective Actions

- Are all possible alternatives considered?
- Is support available? Are responsibilities clear?
- What is our method of ongoing evaluation?
- Will the current containment solution (Correction) taken last until root cause corrective action is fully implemented?
Categories of a Typical Root Cause

- Failure to have a defined policy, procedure or process
- Failure to follow your defined policy, procedure or process
- Poorly defined documented process
- Lack of effective education and training of your employees
- Failure to verify employee training was effective
- Poor supervision
- Lack of information
In determining solutions consider the following:

**Employee Involvement:** The departments and personnel affected by the problem need to be involved in creating the solution.

**Focus on Systems:** The solutions should be focused on systemic issues. Operators do make mistakes, but that is not usually the root cause of the problem.

**Contingency Planning:** All solutions are developed with a certain expectation of success. Critical elements of the solution should have contingency plans available to prevent failure of the entire solution.
How to Verify & Validate Effectiveness of Root Cause Analysis
How to Perform Root Cause Analysis

1. Identify All Possible Causes
2. Narrow the List of Possible Causes
3. Verify the Root Cause
Verification of effectiveness

The verification of effectiveness portion of the process includes both:

**Follow-Up:** A review done by a team member to ensure all corrective actions are implemented as stated

**Assessment:** An independent review to determine if the corrective actions have been effective in preventing recurrence
Assessment

- Once the action has been implemented, you are required to determine that the actions taken were effective.

- In order to determine effectiveness, you must define the criteria by which you measure effectiveness and what is acceptable.

- Assessing effectiveness of actions taken will be a significant step in reducing non-sustaining corrective actions.
Effective Root Cause Analysis

✔ Identifies the true cause of the problem

✔ Leads to permanent corrective action

✔ Actions must be applied to similar processes

✔ May identify several other areas that should be investigated

✔ Preventive steps taken
Follow-Up

Corrective actions must be accomplished as stated and someone must be responsible to assure that the actions were implemented.

When verifying implementation, it is important to take things literally:

• Was everything accomplished as you stated in the report?
• Were the tasks accomplished according to the established timeline?
The CAPA Process (Deming Wheel)
Criteria for Implementing Permanent Action

- Was the Corrective Action effective
- Impact on Customer Satisfaction
- Cost
- Time
- Ease of Implementation
- Scope of Authority
Root Cause/Corrective Action

Major factors for inefficient or ineffective problem solving are failure to:

• Not targeting meaningful problems.
• Not using an effective problem solving process.
• Not getting the necessary functions and “opinion leaders” involved.
• Not translating the problem and solution into dollars.
• Not linking the corrective action system to other products.
• No Follow-through (do the correction and ensure its effective).
CAPA Benefits

- Provides long term solutions
- Prevents recurrences
- Fosters continuous improvement
- Improves customer satisfaction
- Improves profitability
- FDA/FSMA will be basing their inspection frequency on the robustness of your food safety programs
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