



# Corrective and Preventive Action Basics

November 4, 2014

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# Learning Objectives

- Know the purpose of Corrective and Preventive Action
- Have the ability to distinguish between each defined term
- Understand the requirements in 21 CFR 820 Quality System Regulation
- Identify various types of data and tools
- Recognize examples and best practices
- Be aware of compliance concerns

# Purpose of the Corrective and Preventive Action Subsystem

- To collect and analyze information to identify actual and potential product and quality problems
- To investigate product and quality problems and take appropriate and effective corrective or preventive action
- To verify or validate the effectiveness of corrective and preventive actions

# Purpose of the Corrective and Preventive Action Subsystem

- To communicate corrective and preventive actions to the appropriate people
- To provide information for management review
- To document activities

## 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 recurrence.
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 occurrence.

*ISO 9000:2005(E)*

# 21 CFR 820 Regulatory Requirement - Procedures

Establish and maintain procedures for implementing corrective and preventive action

*21 CFR 820.100(a)*



# The Preamble on Procedures

The procedures (for implementing corrective and preventive action) must provide for control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities.

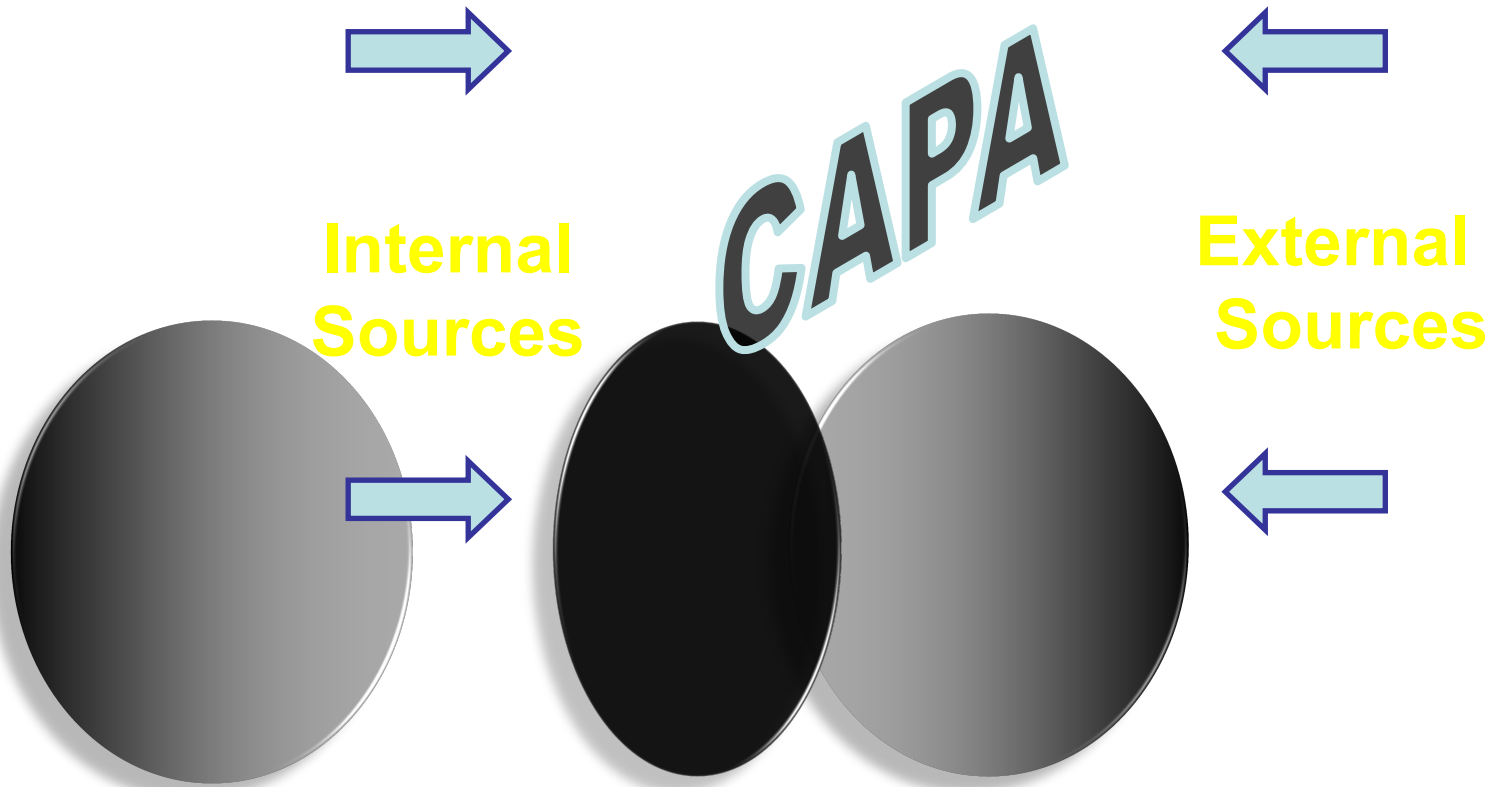
*Preamble, Comment 158*

# Where to Start? Planning

Plans should include...

- I. Establishing Data Sources and Criteria
- II. Measuring and Analysis of Data Sources
- III. Improvement Plans
- IV. Input to Management

# Establishing Data Sources



## Examples of Internal Data Sources

- Process Control Data
- Test/Inspection data
- Device History Records
- Internal Audits
- Nonconforming material reports
- Rework and Scrap/Yield Data
- Training records

## Examples of External Data Sources

- Supplier Controls
- Customers
- Complaints
- Servicing repairs
- Adverse Event Reporting (MDR)
- FDA
- Even similar devices from competitors

# Data Analysis

Analyze 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.

*21 CFR 820.100(a)(1)*

# Approach to Data Analysis

## Non-statistical & Statistical Techniques

- Use a risk-based approach to rank areas,  
Select items with major impact, i.e. Product related or  
Process related  
Proceed with items from high to low impact and  
eventually assure all areas are addressed
- Use of Statistical Methodology; 21 CFR 820.100(a)(1)  
Appropriate statistical methodology shall be employed  
where necessary to detect recurring quality problems

# Investigate to Determine Root Cause

Investigate the cause of nonconformities relating to product, processes, and the quality system

*21 CFR 820.100(a)(2)*



# The Preamble on Investigations

The requirement in this section is broader than the requirement for investigations under Sec. 820.198, because it requires that nonconforming product discovered before or after distribution be investigated to the degree commensurate with the significance and risk of the nonconformity.

*More . . .*

# The Preamble on Investigations

...the requirement in this section applies to process and quality system nonconformities, as well as product nonconformities...if a molding process with its known capabilities has a normal 5 percent rejection rate and that rate rises to 10 percent, an investigation into the nonconformance of the process must be performed.

*Preamble, Comment 161*

# Identify Corrective and Preventive Actions

Identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems

*21 CFR 820.100(a)(3)*

# Identify Action(s) to be taken

- No further action necessary
- Correction
- Corrective Action
- Preventative Action

# The Preamble on Risk and Degree of Corrective and Preventive Action

...the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered. . . .

*Preamble, Comment 159*

# Verify/Validate Corrective and Preventive Actions

Verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device

*21 CFR 820.100(a)(4)*

# The Preamble on Verification and Validation

FDA has revised Sec. 820.100(a)(4) to reflect that preventive, as well as corrective, action must be verified or validated.

*Preamble, Comment 163*

# Implement Corrective and Preventive Actions

Implement and record changes in methods and procedures needed to correct and prevent identified quality problems

*21 CFR 820.100(a)(5)*



# Communicating CAPA Information

- Disseminate information related to quality problems or nonconforming products to those directly responsible for assuring the quality of such product or the prevention of such problems. *21 CFR 820.100(a)(6)*
- Submit relevant information on identified quality problems, as well as corrective and preventive actions, for management review. *21 CFR 820.100(a)(7)*

## The Preamble on CAPA Activities for Management Review

. . . Only certain information need be directed to management. The manufacturer's procedures should clearly define the criteria to be followed to determine what information will be considered "relevant" to the action taken and why. FDA emphasizes that it is always management's responsibility to ensure that all nonconformity issues are handled appropriately.

*Preamble, Comment 164*

# Documenting Corrective Action and Preventive Action Activities

Document all activities required under this section, and their results

*21 CFR 820.100(b)*

# The Preamble on CAPA and Internal Audits and Mgmt Reviews

Two comments stated that the records required under Sec 820.100(b) should be treated as part of the internal audit. FDA disagrees with these comments...FDA has the authority to review such records and the obligation to do so to protect the public health. . . Manufacturers will be required to make this information readily available to an FDA investigator

*Preamble, comments 166*

# FDA Inspection

Manufacturers should consider that their Corrective Action and Preventive Action documentation can demonstrate to FDA that the manufacturer's quality system is effective and enables the manufacturer to identify problems quickly and implement effective corrective and preventive actions

# Guidance Available

- GHTF: Quality Management System  
Medical Devices – [Guidance on corrective action and preventive action and related QMS processes;](#)  
SG3; 2010
- GHTF: Quality Management System  
Medical devices - [Nonconformity Grading System for Regulatory Purposes and Information Exchange;](#)  
SG3; 2012

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## 3. Division of Industry and Consumer Education (DICE)

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- Phone: 1(800) 638-2014 or (301) 796-7100 (Live Agents 9am – 4:30 pm EST)
- **Web Homepage:**  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm>