# Corrective and Preventive Action Subsystem

**FDA Small Business**
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**The 7 Subsystems of a Quality System**

# Objectives

- Understand the parts of the Corrective and Preventive Action Subsystem
- Know the Subsystem's purpose and definitions
- Identify 21 CFR 820 Quality System (QS) Regulatory requirements
- Discuss various types of data and tools
- Provide examples
- Identify compliance concerns

# Parts of Corrective and Preventive Action Subsystem

- Complaint Handling
- Non-Conforming Products
- Corrective and Preventive Action

# Purpose of the Corrective and Preventive Action Subsystem

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

# Purpose of the Corrective and Preventive Action Subsystem

- To communicate those actions; i.e. corrections, corrective actions and preventive actions to the appropriate people
- To provide information for management review
- To document activities

# Definition: Complaint

***Complaint***

Any written, electronic, or oral communication that **alleges** deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

*21 CFR 820.3(b)*

# Definitions: Nonconformity and Rework

***Nonconformity*** means the non-fulfillment of a specified requirement. *21 CFR 820.3(q)*

***Rework*** means action taken on a nonconforming product so it will fulfill the specified DMR requirements before it is released for distribution. *21 CFR 820.3(x)*

# 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)*

# Complaint Files Regulatory Requirements

**All manufacturers must:**

- Maintain complaint files.
- Designate a formal complaint handling unit.
- Establish and maintain procedures for receiving, reviewing, and evaluating complaints.

*21 CFR 820.198*

# Complaint Files Continued

**Procedures must ensure:**

- All complaints are processed in a uniform and timely manner.
- Oral complaints are documented when received.
- Complaints are reviewed and evaluated to determine if an investigation is needed. When no investigation is made, document why and who made the decision.

# Complaint Files Continued

**Complaints and interaction with Medical Device Reporting (MDR):**

- Complaints are evaluated to determine whether the complaint represents a reportable event, Medical Device Report (MDR), according to 21 CFR 803.

- Promptly review, evaluate and investigate complaints representing an MDR.
  - Such complaints should be maintained in a separate portion of the complaint file or otherwise clearly identified.

# Complaint Files Continued

Records of investigation will include determination of:

- Identifiers related to the device and reported event
- If MDR reportable:
  - Whether the device failed to meet specifications
  - Whether the device was being used for treatment or diagnosis
  - If applicable, the relationship of the device to the reported event

Complaint files need to be reasonably accessible to the manufacturer

# Non-conforming Product Regulatory Requirements

Control of Non-conforming Product

Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

*21 CFR 820.90*

# The Nonconformity Should:

- Be written in a clear, concise manner and self explanatory.
- Be supported by objective evidence.
- Identify the specific requirements which have not been met, including regulatory requirements, standards and procedures and specified requirement established by the firm

# Non-conforming Product Requirements continued

The procedure must address the following.

- Identification
- Evaluation, including determination of the need to investigate and notification to those responsible for the non-conformance
- Segregation and
- Disposition of nonconforming product.

The evaluation and any investigation must be documented.

# Preamble on Investigations and Trending

The evaluation process addressed in the procedure “shall include a determination of the need for an investigation”. Therefore, the procedures will need to set forth the manufacturer’s SOP on when investigations will take place and provisions for trending and/or monitoring the situation in the future.

***Preamble, Comment 155***

# Non-conforming Product Requirements continued

Nonconformity review and disposition.

Manufacturer's procedures will…

- Define responsibility for the review
- Authority for the disposition
- Set forth the review and disposition process and document the disposition
- Document justification for use including signature of the individuals authorizing it.

*21 CFR 820.90(b)(1)*

# Non-conforming Product Requirements continued

Established Rework procedures will include:

- Retesting and Revaluation after rework
- Rework and retesting activities
- Determination of any adverse effect from the rework
- Any adverse effects will be documented in the Device History Record

*21 CFR 820.90(b)(2)*

# Non-Conformance Grading Suggestions

Examples of grading matrices and criteria that can be used:

- **Initial Grade Matrix**
  - QMS Impact – Indirect and direct
  - Occurrence – first time or repeat
- **Escalation Rules** (added to initial grade)
  - Absence of documented process requirements
  - Medical Device Release outside firms control
- **Final Nonconformity Grade**

# Corrective and Preventive Action Regulatory Requirements 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.

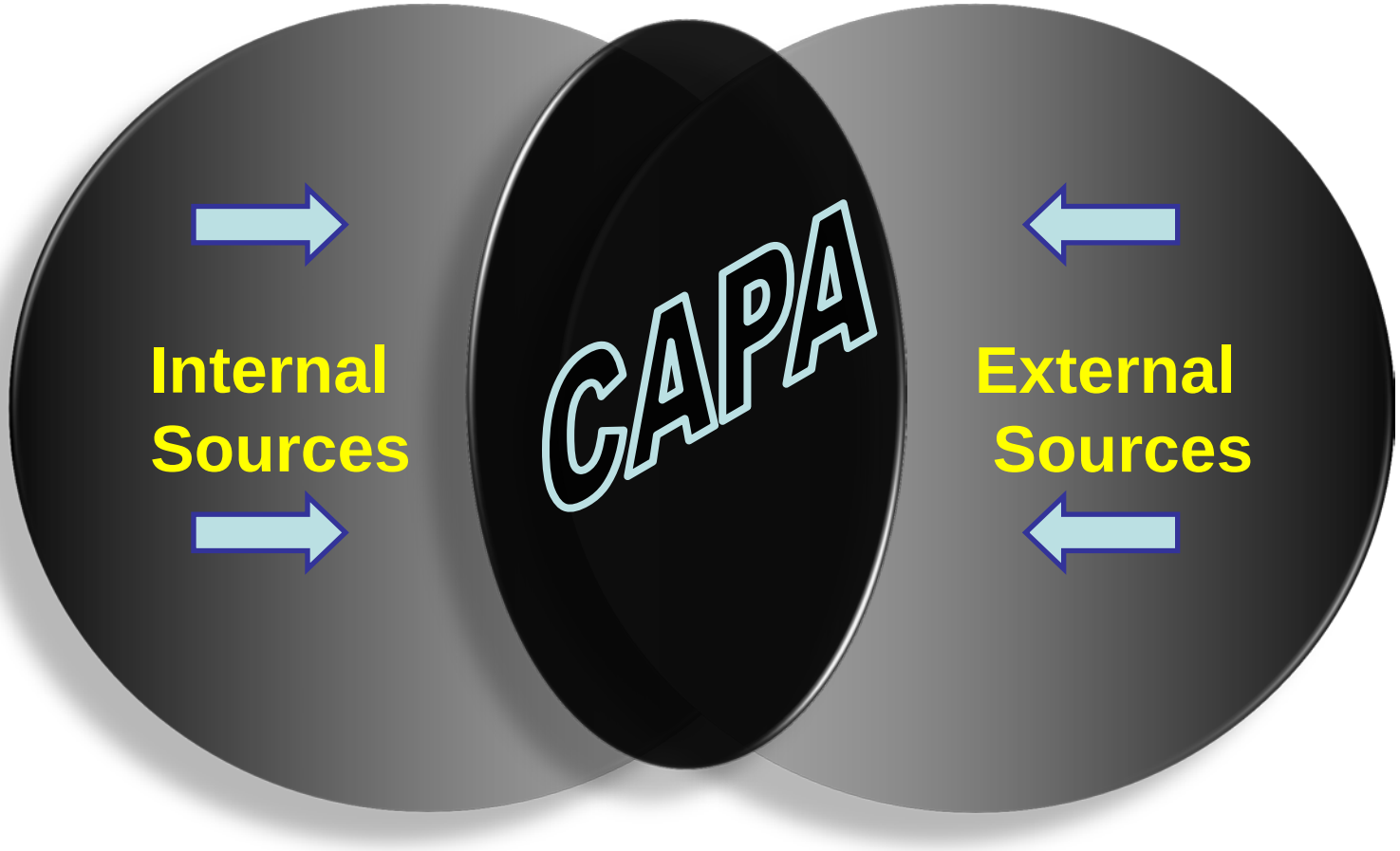
***Preamble, Comment 158***

# 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
- Scrap/Yield Data
- Rework
- Training records

# Examples of External Data Sources

- Supplier Controls
- Customers
- Complaints
- Product Warranty 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

  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
- Preventive 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.

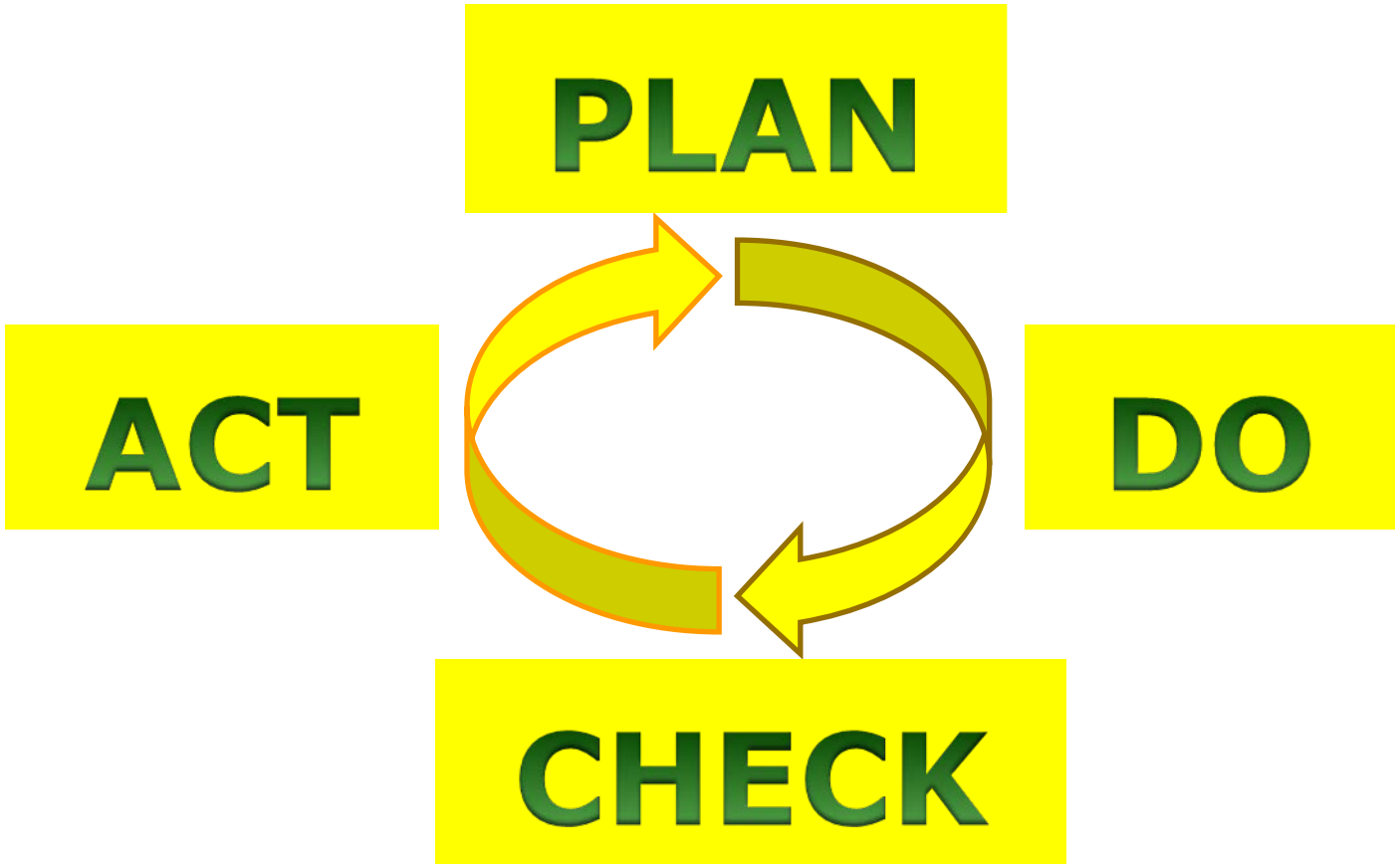
***Preamble, Comment 163***

# 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)*

# Close the Loop



# 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, Comment 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 them to identify problems quickly and implement effective corrective and preventive actions.

# FY 2013 FDA Inspectional Data
# FDA 483 Observations

- **1099** 483s issued for Devices, Source of data: http://www.fda.gov/ICECI/Inspections/ucm381526.htm#devices
- Most frequent 483 Observations, 4 of top ten.

  #1 - 21 CFR 820.100(a) – frequency 378 times

  #2 - 21 CFR 820.198(a) – frequency 245 times

  #3 - 21 CFR 820.100(b) – frequency 133 times

  #7 - 21 CFR 820.90(a) – frequency 98 times

# Annual CY CAPA Subsystem Data Warning Letters (EIR database)

| Year | # w/ CAPA cite | % |
|---|---|---|
| **2012** | **143** | **87** |
| 2011 | 104 | 85 |
| 2010 | 81 | 91 |
| 2009 | 68 | 88 |
| 2008 | 86 | 88 |
| 2007 | 62 | 84 |
| 2006 | 69 | 87 |
| 2005 | 85 | 88 |
| 2004 | 89 | 79 |

# Most Frequent 2012 QS Warning Letter Cites

| Citation | QS Subsystem | Number of WL Cites |
|---|---|---|
| **21 CFR 820.198(a)** | **CAPA** | **82** |
| **21 CFR 820.100(a)** | **CAPA** | **78** |
| 21 CFR 820.184 | DOC | 51 |
| 21 CFR 820.75(a) | P&PC | 49 |
| 21 CFR 820.22 | MGMT | 43 |
| 21 CFR 820.30(g) | DES | 43 |
| 21 CFR 820.50 | P&PC | 36 |
| **21 CFR 820.90(a)** | **CAPA** | **31** |
| 21 CFR 820.181 | DOC | 31 |
| 21 CFR 820.30(i) | DES | 30 |

# GHTF Guidance Available

- GHTF: Quality Management System

  Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange; SG3; 2012

- GHTF: Quality Management System

  Medical Devices – Guidance on corrective action and preventive action and related QMS processes; SG3; 2010

# Additional FDA Guidance Available On Our Website

- Compliance Program Guidance Manual for Inspection of Medical Device Manufacturers (CP 7382.845)
- QSIT: http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm

**THANK YOU**

Center for Devices and Radiological Health
CDRH