CAPA Overview Training
Ground Rules

- Please put your cell phones on vibrate.
- Actively participate and ask questions freely. This will help you learn.
- You must be in attendance for the entire training session to receive credit.
- Offer any pertinent situations/examples that have arisen in your work area or from past work experience.
- Issues/questions that cannot be resolved/answered during this program will be placed in a “Parking Lot”.
CAPA Overview Training

In today’s CAPA Overview training, we will discuss information broken into the following learning segments:

- Segment #1: CAPA General Information
- Segment #2: Identification of the Problem
- Segment #3: Evaluation, Investigation and Analysis of the Problem
- Segment #4: Development of an Action Plan
- Segment #5: Implementation of the Action Plan and Follow-up
Learning Segment #1

CAPA General Information
**WHAT is CAPA?**

- **CAPA** refers to corrective and preventative actions.

- CAPA is a concept within Good Manufacturing Practices (GMP).

- CAPA focuses on the systematic investigation of discrepancies (failures and/or deviations) in an attempt to prevent their recurrence.

- CAPA is part of the overall quality management system (QMS)
**WHAT** is the Difference Between Corrective Actions and Preventive Actions?

A corrective action is a term that encompasses the process of reacting to product problems, customer complaints or other nonconformities and fixing them.

The process includes:

- Reviewing and defining the problem or nonconformity
- Finding the cause of the problem
- Developing an action plan to correct the problem and prevent a recurrence
- Implementing the plan
- Evaluating the effectiveness of the correction
WHAT is the Difference Between Corrective Actions and Preventive Actions?

A preventive action is a process for detecting potential problems or nonconformance’s and eliminating them.

The process includes:

- Identify the potential problem or nonconformance
- Find the cause of the potential problem
- Develop a plan to prevent the occurrence.
- Implement the plan
- Review the actions taken and the effectiveness in preventing the problem.
WHAT is the Objective of CAPA?

- The CAPA process ensures that corrective and preventive actions are effective and that systematic investigation of the failure incidence is pivotal in identifying the corrective and preventive actions undertaken.

- CAPA must be part of an integrated Quality Management system that collects data on existing and potential problems, investigates and analyzes the data, digs down to the root cause, addresses the issue, institutes specific procedures to avoid similar problems in the future and documents the entire process.

- CAPA is most effective when it is part of the culture of a company, pervading every organizational level and department.
WHAT do the regulations say?

- Establishing a CAPA system is a CGMP requirement for medical device manufacturers producing product for the US (21 CFR 820.100).

- Drug CGMPs. Conducting certain investigations and documenting and justifying deviations is required for manufacturers making product for the US. Inadequate investigations are a frequent CGMP deficiency (21 CFR 211.192).

- Preclinical Requirements. Taking corrective action is required in the GLPs (21 CFR 58) for testing facility management (21 CFR 58.31), the study director (21 CFR 58.33), Clinical Requirements. And taking effective corrective action is implied in the GCPs.

- Relevant sections include but aren’t limited to the Responsibilities of Sponsors (21 CFR 812.40) and Responsibilities of Sponsors and Investigators (21 CFR 312 Subpart D).
WHY do we need a CAPA Process?

Effective CAPA (correction action, preventive action) management is more than just an important regulatory requirement. It is a good business practice that brings many benefits.

A strong CAPA program can:

- reduce liability
- improve customer satisfaction
- prevent major financial losses
- strengthen a company’s reputation
WHY do we need a CAPA Process?

Additionally, a strong CAPA program can:

- quickly identify and address deficiencies and zero in on the sources of potential problems and prevent them
- drive a company’s continual improvement efforts
- help achieve operational excellence both in product and process which translates to increased performance and greater revenue.
WHO Participates in the CAPA process?

- Quality Assurance and Quality Control
- Manufacturing
- Packaging
- IT
- Facilities
- External Consultants
**WHAT** are the Major Components of a CAPA system?

- The *Identification* of the problem, nonconformity, or incident or the potential problem, nonconformity, or incident.

- An *Evaluation* of the magnitude of the problem and potential impact on the company.

- The development of an *Investigation* procedure with assignments of responsibility.

- Performing a thorough *Analysis* of the problem with appropriate documentation.

- Creating an *Action Plan* listing all the tasks that must be completed to correct and/or prevent the problem.

- The *Implementation* the plan.

- A thorough *Follow up* with verification of the completion of all tasks, and an assessment of the appropriateness and effectiveness of the actions taken.
Learning Segment #2

Identification of the Problem
The specific origin of the information that initiated this action is recorded.

Documenting the source of the information can be very useful when conducting an investigation into the problem and implementing the action plan that is created.

Documentation also provides data for evaluating the effectiveness of the quality system and facilitate communicating the completion of the action to the appropriate individuals or departments.
Reporting the Source of the Problem (cont’d)

Examples of possible sources might include:

- Service Request
- Internal Quality Audit
- Customer Complaint / Concern
- Quality Assurance Inspection
- Staff Observation
- Trending Data
- Failure Mode Analysis
- Risk Assessment
- Process Performance
- Monitoring Management Review
Explaining the Problem

- A complete description of the problem is written.
- The description should be concise but must contain sufficient information to assure that the problem can be easily understood from reading the explanation.
Determining and Preparing Evidence

- List the specific information available that demonstrates that the problem does exist.

- An example might be:
  - The evidence for a product defect may be a high percentage of service requests or product returns.
  - The evidence for a potential equipment problem may be steadily increasing downtime.
Leader’s Guide
CAPA Overview Training

Please print and read this document prior to class. It informs you how to produce the other documents and components of this program.

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Program Information

Program Title:
CAPA Overview Training

Program Description:
The primary purpose of this program is to provide an overview of the CAPA process.

Program Objectives:
At the end of this program participants will be able to:
1. Explain CAPA General Information.
2. Explain the CAPA process, including
   - Identification of the Problem
   - Evaluation, Investigation and Analysis of the Problem
   - Development of an Action Plan
   - Implementation of the Action Plan and Follow-up

Intended Audience:
All employees.

Recommended Audience Size:
15 to 20 participants

Training Frequency:
Deliver to new employees and/or employees with CAPA responsibilities.

Estimated Presentation Time:
2.0 hours (Includes time for presentation, questions and answers, and assessment)

Estimated Preparation Time:
1 hour

Presentation Materials:
- PowerPoint slide deck: CAPA Overview Training
- Knowledge Assessment
- Knowledge Assessment Answer Key
- Training Sign-in Sheet (not provided in Leader’s Guide)

Presentation Equipment:
- Slide projector
- Computer
- Screen
- Pens/pencils for participants
- Flip chart/markers
- Room to accommodate 15-20 people

Presentation Format:
• PowerPoint presentation
• Large group discussion

Assessment Requirements:

☐ Knowledge Assessment
☐ Knowledge Assessment Answer Key
☐ 80% completion for passing grade
Program Implementation

Program Preparation

Prepare the Materials

In addition to this Leader’s Guide, there are three pieces to be developed for this program:

1. Slide handouts
2. Knowledge Assessment
3. Knowledge Assessment Answer Key

To produce the Slide handouts:

1. Open the PowerPoint file.
2. Go to File, then Print.
3. Once the Print command box comes up, make sure to check for these settings:
   - Print Handouts 3 slides per page
   - Print Range: All
   - Number of Copies: (enter total for the number of class attendees)
4. Left click on OK

It is suggested that you print one copy of the worksheet and use a copy machine to duplicate copies for each program participant. It is a good idea to have a couple of additional copies of each worksheet available for participants who attend the presentation at the last minute.

To produce the Knowledge Assessment

You may print a copy from the Appendix OR:

1. Open the Word document.
2. Go to File, then Print
3. Once the Print command box comes up, make sure to check for these settings:
   - Print Range: All
   - Number of Copies: 1
4. Left click on OK

It is suggested you print out one copy of the Knowledge Assessment and use a copy machine to duplicate copies for each program participant. It is a good idea to have a couple of additional copies of the assessment for participants who attend the presentation at the last minute.

To produce the Knowledge Assessment Answer Key

You may print a copy from the Appendix OR:

1. Open the Word document.
2. Go to File, then Print
3. Once the Print command box comes up, make sure to check for these settings:
   - Print Range: All
   - Number of Copies: 1
4. Left click on OK
Prepare the Classroom

Visit the room where you will be making the presentation ahead of time. Make sure the projection system and computer are plugged in to the electric outlet, connected to each other and operate properly. Make sure the screen operates correctly. Place a flip chart at the front of the room.

Prepare Yourself

The program consists of a Lesson Plan to guide you through the presentation. You should “walk” through the presentation at least once to ensure you are familiar with the presentation and what you will say. A Lesson Plan is provided to guide you in the important points to cover and discuss with the participants.

Program Presentation

Follow the provided Lesson Plan. If you do, you’ll be sure to make a complete presentation.

Prior to beginning the program, hand out copies of the slides to the participants. These pages have space for the participants to use to take notes during the presentation. Also, make sure that each person has a pen or a pencil to take notes.

Program Wrap-Up

Administer the Knowledge Assessment at the end of the training program. The Facilitator will grade the assessment, with 80% a passing score. If remediation is required, review the material with the participant, and re-administer the test.
Lesson Plan

Slide 1

Introduce yourself (if necessary) and then introduce this training program by saying:

*Welcome to CAPA Overview Training!*

*This training will present you with an overview the CAPA process – from general information regarding the process to topics like identification, evaluation, investigation, analysis of the problem and finally the development and implementation of Action Plans.*

*So let’s get started!*

Slide 2

Now say:

*First of all, let’s cover a few ground rules.*

Review bulleted items.

Slide 3

Review program objectives.
Introduce Learning Segment #1 – CAPA General Information by saying:

In this first learning segment we will cover topics such as:

- **What is CAPA?**
- **Difference between Corrective Actions and Preventive Actions.**
- **Objectives of CAPA.**
- **CAPA regulations.**
- **Importance of a CAPA process.**
- **CAPA responsibilities.**
- **Major components of a CAPA system.**

Define CAPA using bulleted items on slide.

Now say:

*Understanding the difference between Corrective Actions and Preventive Actions is key to understanding the entire CAPA process. Let's define a Corrective Action now.*

Review slide to explain Corrective Actions.

Ask participants for examples of Corrective Actions and record them on the flipchart.
Slide 7

**WHAT is the Difference Between Corrective Actions and Preventive Actions?**

A preventive action is a process for detecting potential problems or nonconformances and eliminating them.

The process includes:

- Identify the potential problem or nonconformance
- Find the cause of the potential problem
- Develop a plan to prevent the occurrence
- Implement the plan
- Review the actions taken and the effectiveness in preventing the problem.

Review slide to define a Preventive Action.

Then say:

*As you can see, there is a significant difference between the two.*

Ask participants for examples of Preventive Actions and record them on the flipchart.

Compare Corrective Action examples with Preventive Action examples and discuss to clarify (if necessary).

Slide 8

**WHAT is the Objective of CAPA?**

- The CAPA process ensures that corrective and preventive actions are effective and that systematic investigation of the failure incidence is pivotal in identifying the corrective and preventive actions undertaken.

- CAPA must be part of an integrated Quality Management system that collects data on existing and potential problems, investigates and analyzes the data, digs down to the root cause, addresses the issue, institutes specific procedures to avoid similar problems in the future and documents the entire process.

- CAPA is most effective when it is part of the culture of a company, pervading every organizational level and department.

Review slide to identify the objectives of CAPA.

Then say:

*So we’ve now defined CAPA, identified the difference between Corrective and Preventive Actions and identified objectives for CAPA.*

*You may now be thinking – why do we need this?*

Ask participants to provide reasons for establishing and maintaining a CAPA process/system.

Record responses on flipchart and then move on to the next slide.

Slide 9

**WHAT do the regulations say?**

- Establishing a CAPA system is a CGMP requirement for medical device manufacturers producing product for the US (21 CFR 820.190).

- Drug CGMPs. Conducting certain investigations and documenting and justifying deviations is required for manufacturers making product for the US. Inadequate investigations are a frequent CGMP deficiency (21 CFR 211.182).

- Preclinical Requirements. Taking corrective action is required in the CLPs (21 CFR 820) for testing, facility management (21 CFR 863.11), the study director (21 CFR 863.3), Clinical Requirements. And taking effective corrective action is implied in the CLPs.

- Relevant sections include but aren’t limited to the Responsibilities of Sponsors (21 CFR B12.40) and Responsibilities of Sponsors and Investigators (21 CFR 312 Subpart J).

You might say:

*One of the primary reasons for establishing and maintaining a CAPA system is to ensure compliance.*

Review bulleted items on slide.

- CAPA system establishment.
- Drug cGMPs.
- Pre-clinical requirements.
- Relevant sections of the Code.
Effective CAPA management is more than just an important regulatory requirement – it makes good business sense by reducing liability, improving customer satisfaction, preventing major financial losses and strengthening our company’s reputation.

Review slide.

Continue discussion of why a CAPA process is needed using the slide.

Then ask the question:

Now that we understand the importance of the CAPA process, who do you think participates in it?

Record responses on flipchart and then move to the next slide.

Review bulleted items on slide and compare to participant responses recorded on flipchart.
Here are the major components of an effective CAPA system.

Review items on slide and provide examples as necessary.

Then ask:

Are there any questions on this first learning segment?

Review Learning Segment #1 topics as necessary for clarification.

- What is CAPA?
- Difference between Corrective Actions and Preventive Actions.
- Objectives of CAPA.
- CAPA regulations.
- Importance of a CAPA process.
- CAPA responsibilities.
- Major components of a CAPA system.

You might say:

Now let’s move on to Learning Segment #2 where we will discuss Identification of the Problem.

This learning segment will include the topics:

- Reporting the source of the problem.
- Explaining the problem.
- Determining and preparing evidence.
Now say:

*First of all, the source of the problem must be reported. This will involve a good bit of documentation – which is critical to an effective investigation.*

Review slide.

Continue discussion of Reporting the Source of the Problem by identifying possible sources using slide.

Ask for input from the group:

*What are some specific examples of possible sources that may fit into these items?*

*For example. Can you give me a specific situation where an Internal Quality Audit resulted in a problem being identified? How about a Risk Assessment? Trending Data?*

Record responses on flipchart.
Slide 17

Once the problem has been reported, you will need to explain the problem.

Review slide and ask the question:

What types of questions would you want answers to if you were explaining a problem?

Potential answers can include (but are not limited to):

- What exactly happened?
- Was product impacted? If so, how? How much?
- What data or documentation is available?
- Isolated incident or systemic situation?

Slide 18

Then you’ll need to determine and prepare the evidence.

Review slide and then ask for additional examples of evidence. Examples could include:

- Scale tickets.
- Cleaning logs.
- Process-controller data.

Then ask:

Are there any questions on this 2nd learning segment?

Review Learning Segment #2 topics as necessary for clarification.

- Reporting the source of the problem.
- Explaining the problem.
- Determining and preparing evidence.
Introduce Learning Segment #3 by saying:

*Our third learning segment in this course is Evaluation, Investigation and Analysis.*

Then say:

*When you evaluate the situation, you will need to determine the need for action, level of action, and potential impact.*

Review bulleted items on slide.

Review slide. You might say:

*First of all, you need to look at the potential impact. This is where you will explain exactly why the problem is a concern.*

*This can include identifying the potential impact of the problem in terms of costs, product quality and so-on.*

Ask the question:

*Has anyone here been involved in evaluating the potential impact of a problem? If so, could you give us some specific examples?*
Now say:

Next is Assessment of Risk. This goes hand-in-hand with identifying the potential impact. During this process the seriousness of the problem is assessed, which will drive actions taken later.

Review slide and then say:

Let’s use another example here as well. Say an operator is weighing an API using a scale that is out of calibration and it is not known for how long this has been going on. Will this situation have a high degree of risk or a high priority?

You might say:

Once the Assessment of Risk is determined, Remedial Action(s) must be identified. Remedial Actions are activities designed to correct the problem and minimize further risk. These actions must be documented and explained thoroughly as they will become part of the CAPA document.

Review slide and ask for any questions regarding this topic – Evaluation.

Introduce Investigation discussion by saying:

Once Evaluation is complete an Investigation is initiated. This will involve the development of an Investigation Process or Plan which will identify objectives, procedures, responsibilities, resources and documentation.

This process will ensure that the investigation is complete and nothing is missed.
1. **True or False:**

   Corrective action encompasses the process of reacting to product problems while preventive action is a process for detecting potential problems or nonconformance’s and eliminating them.

   a. True
   b. False

2. **Put the following CAPA processes in the correct order.**

   2. Evaluation, Investigation and Analysis
   1. Identification
   4. Implementation Action Plan and Following Up
   3. Creating an Action Plan

3. **Circle all that apply:**

   Which of the following is a possible source of a problem?

   a. Customer Complaint
   b. Risk Assessment
   c. Trending Data
   d. Internal Quality Audit
4. **True or False:**
   During the problem evaluation stage, the problem is evaluated to determine both the need for action and the level of action required.
   
   a. True
   b. False

5. **Circle all that apply:**
   Which of the following is included in the Investigation Process?
   
   a. **An objective for the actions that will be taken**
   b. The response of the human resources department
   c. **The personnel that will be responsible**
   d. The action plan and follow-up results

6. **Multiple Choice:**
   The Investigation Procedure contains a set of specific instructions are created that outline what must be done to determine the contributing and ______ ________of the problem.
   
   a. Financial Impact
   b. Personnel Impact
   c. **Root Cause**
   d. Remedial Actions