

# Root Cause Analysis & CAPA Training

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## ROOT CAUSE ANALYSIS & CAPA



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## FINDING THE ROOT CAUSE

Determining Effective  
Corrective & Preventive Action  
via Root Cause Analysis

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## RCA AND CAPA

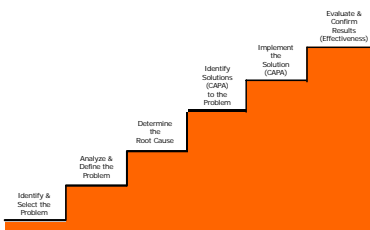
### Course Objectives

- ✓ Define CAPA requirements (FDA QSR & ISO 13485)
- ✓ Discuss FDA's inspection technique with regard to the CAPA subsystem and CAPA requirements
- ✓ Review the Six Step Method for RCA and the relationship to FDA's QSIT CAPA subsystem
- ✓ Present RCA techniques/methods
- ✓ Identify key terms and definitions
- ✓ Assess level of CAPA needed
- ✓ Evaluate adequacy of CAPA's

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## Six Step Method



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The Root Cause Analysis and CAPA module is ideal for those organizations looking to comply with FDA QSR, ISO 9000 and/or ISO 13485 requirements for CAPA. The requirements are presented in a manner to allow any organization, regardless of size or product type, to implement an effective CAPA program.

The Root Cause Analysis and CAPA module was developed for individuals or teams involved with or responsible for determining corrective and preventive action in order to prevent problems from recurring. The RCA and CAPA module is formatted to provide personnel with a complete knowledge and understanding of the FDA QSR and ISO 13485 CAPA requirements. The requirements are illustrated using the FDA Quality System Inspection Technique (QSIT) and Six Step Method.

Various techniques or methods for performing root cause analysis are also discussed to facilitate effective corrective and preventive action. Determination of the level of CAPA required is also discussed with respect to Patient Risk and Product/Process Risk.


Each module includes a CD ROM of the Adobe Acrobat® formatted presentation, an Instructor's Manual, a comprehension exam and a 3-per-page master presentation handout. Unlimited copies of the comprehension exam and 3-per-page presentation handout may be made, however the CD-ROM and Instructor's Manual may not be reproduced or copied. Completion of the comprehension exam provides a record of training and measure of effectiveness.

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# Root Cause Analysis & CAPA Training

## CAPA REQUIREMENT



FDA: 820.100(a)  
ISO 13485: 8.5.2, 8.5.3

Document procedures for implementing corrective and preventive action

*Why?* To correct and prevent poor quality product as well as poor practices

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Each presentation page has “train-the-trainer” notes, as needed. (See Figure 1 & 2) The notes page clarifies and/or emphasizes the slide contents and may provide an example of how a particular requirement might be satisfied. The notes are included in the Instructor’s Manual and provide a unique and invaluable training aid.

## CAPA REQUIREMENT

*Notes Pages*

To correct and prevent existing problems from recurring and identify and prevent potential problems from occurring, a manufacturer is required to establish procedures for implementing corrective and preventive action.

The reason for doing this is to correct and prevent poor practices, not simply bad product.

As a result, the first thing an Investigator will verify is that a procedure exists that documents how the organization intends to meet the requirements for those elements outlined in 21 CFR 820.100 and/or ISO 13485 sections 8.5.2 and 8.5.3.

Figure 1

## DATA ANALYSIS & PROBLEM DEFINITION

The Five W’s

**WHAT** (Qualitative)

- Purpose: Describe the problem or nonconformance
- Example: Customer product performance expectations for wear time were not met

**WHAT** (Quantitative)

- Purpose: Describe the problem as to magnitude or risk
- Example: Customer was averaging a 5-day wear time and now only getting 3-days

**WHERE or HOW**

- Purpose: Location of the problem or method for reporting
- Example: Customer via complaint process

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## DATA ANALYSIS & PROBLEM DEFINITION

*“The Five W’s”*

*Notes Pages*

Effective problem analysis requires asking the right questions and organizing the answers. Asking the 5W’s may aid in obtaining some critical information needed to accurately define the problem.

**What** was the problem and/or **what** do we want to prevent from recurring?

Customer product expectations were not met – e.g. customer not happy with product performance

**What** is the significance of the problem?

Sometimes problems noted in one area may be prevalent in other areas as well – e.g. systematic vs. isolated. For example, problems noted in complaint records should be compared with similar trends noted in returned goods and acceptance activity information.

**Where** or **how** the problem was observed or discovered?

Often a detailed process flow is an effective way to identify where in the process you are having a problem or there is potential for a problem.

Figure 2