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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CAPA REQUIREMENT

F: 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

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.

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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