COBBLESTONE

COURSE ID 2089

How to Conduct Robust Root Cause Investigations for CAPA

DIRECTED BY

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9 HOUR

ACCREDITED COURSE

Course Topics Include:

- Describing the Problem / Deviation
- Gathering Pertinent Facts
- Tools and Techniques to Identify Possible Causes
- Determining Effective Corrective/Preventive Actions
- How to Verify the Corrective/Preventive Actions
- Real Case Studies & Break Out Sessions

about the course

One of the most common FDA 483 and Warning Letter citations continues to be inadequate investigations. The FDA uses the investigation reports and investigation trends to identify potential quality problems in all areas of the company. Ultimately, inadequate investigations can lead to 483 citations, Warning Letters, release of sub-standard product, or product recall. Furthermore, costly and time-consuming system remediation may be required.

Having a procedure on Deviation Investigations is not enough. It is the content and conclusions of the investigations themselves that truly count. Doing a proper root cause analysis, gathering evidence and ensuring a sustainable corrective action is key to a proper deviation investigation.

This 9-hour accredited training will help attendees understand the fundamental investigation steps and skill sets. Key focus will be placed on identification and initial reporting of deviations, fact/evidence gathering, and arriving at the correct root cause and CAPA. The importance of investigation planning, critical thinking skills and effective preventative action plans will also be discussed.

Root Cause Analysis (RCA) is an important technique practiced by many successful companies. It is used to determine the Corrective Action and Preventive Action CAPA procedures that are mandatory for the Quality Management Systems (QMS).

This training improves the way you analyze, document, and verify the root causes of a problem so that you can prevent their recurrence.

This course will also include discussions on proper CAPA system maintenance, documentation of the Corrective and Preventative Actions and developing a robust CAPA plan. It will give tips on how to develop CAPAs pertaining to longer term projects and ensure they stay on track.

who should attend

This is an informative and interactive seminar for professionals in the pharmaceutical, biological, and medical device industries who conduct deviations, Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) investigations, especially for professionals in the following disciplines:

• Quality Control Analysts	• R&D
• Manufacturing	• Product/Process Development
• Quality Assurance	• Engineering

learning objectives

Upon completion of this course, you will be able to:

- Discuss what to do when problems occur
- Outline the requirements of the Deviation and procedure including the deviation report
- Choose the most appropriate Root Cause Analysis methods for the situation
- Discuss how to conduct the deviation and the tools to be used in the process
- Review and discuss an example deviation using the tools suggested
- Outline the requirements of the CAPA process and procedure including building a CAPA file
- Establishing a CAPA plan: project summary, individual responsibilities and expected completion dates
- Managing and Overseeing of the CAPA system and its documentation

course outline

Review of Learning Objectives/Introduction
Review of FDA and Regulatory Requirements for Investigations, Root Cause and CAPA
– FDA and EU requirements

What is the definition of a deviation?
– Types of Deviations
– Identification of Deviations
– Classifications of deviations
– Break out session
– Classifying Deviations

Conducting the Investigation
– Interviews – dos and don'ts
– Source Documents/Evidence
– Break out session – Using tools to conduct the investigation

Determining Root Cause and Corrective/Preventative Action

- Methods of Root Cause
- Review of case studies using root cause
- Break out session-Using Root Cause Tools

Key Elements of the Investigation Report

- Documentation
- Product Impact
- Training
- Expectations from Regulators
- Break Out session – Finding the errors in real life industry deviations

Definition of a CAPA

- When a CAPA is needed
- Development of the essential pieces of a robust CAPA plan
- Break out session – Determining which deviations require a CAPA

Establishment of the CAPA Plan

- Project Summary development
- Responsibilities of individuals involved
- Establishing Completion Dates
- Creating meaningful effectiveness checks
- Break out session-What is an effective CAPA?

Management of the CAPA System

- Maintaining proper documentation of the CAPA plans
- Ensuring CAPA plans are progressing
- Proper close out of CAPA plans
- Break out session – writing your own CAPA
- A Proper CAPA plan
- e-CAPA
- Break-out Session

Summary

Assessment Opportunity

course instructor

Louis Angelucci, is a pharmaceutical professional with over 20 years' experience in Quality Assurance, Quality Control, Regulatory Affairs, Validation, consent decree remediation as well as cGMP Compliance in the Medical Device and Pharmaceutical industries. He has worked for several well-known companies including Johnson & Johnson, Bristol-Meyer Squibb, Pfizer, Schering Plough and Merck. His experience has been either as a direct employee or as a contracting consultant while employed at Foster Wheeler and Aker Kvaerner. As a consultant Mr. Angelucci has worked at various project locations domestically and in Europe and Asia.

Mr. Angelucci is a degreed engineer with two master's degrees in engineering, holds industry certifications with ASQ as a CQE, CQA and CPGP. He is currently the ASQ Philadelphia chapter Education Chair. In addition, he holds a PMP certification through the Project Management Institute. He has published numerous articles on the subjects of Validation and compliance and has been a speaker to industry groups such as ISPE, IVT, DIA, PDA and ASQ.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 9 contact hours, or .9 CEUs. For further information, visit www.iacet.org