SkillsPlus Inc.
INTERNATIONAL

On-Site Series

Root Cause Analysis for Better Investigations

Purpose

To conduct or facilitate individual or team-based investigations which identifies the real root cause of deviations, solves problems, get results and complies with FDA expectations.

Objectives

At the completion of the class, students will be able to:

1. Identify the real deviation statement.
2. Use the most common tools and techniques identify the root cause of the deviation.
3. Determine product and material impact.
4. Determine the best corrective action.
5. Generate an objectively select the best preventive actions.
6. Assess the risk of implementing any corrective action and preventive action.
7. Develop a contingency plan to preventive action implementation.
8. Create follow up action metrics.

Prerequisite

Attendees in this class should have a solid understanding of the GMP regulations.

Who should attend this class?

Anyone who is responsible for conducting deviation investigations, or who reviews the investigation work completed by others, should attend this class.

About the class

1. This class uses current deviations to practice the techniques taught.
2. The optional final exam is approximately 25 questions.
3. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
4. This class can accommodate up to 25 people.
5. Duration: 8 hours.

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Topics Covered

CGMPs and Investigations

1. The CGMPs and investigations
2. Investigation related observations

Tools and Techniques

1. Brainstorming and brain writing
2. Distinctions
3. Fishbone diagrams
4. 5-Why's
5. Flow charting
6. Function analysis
7. Decision matrix
8. Risk assessment
9. Questioning
10. Charts and graphs
11. Priorities
12. Consensus

Deviation Statement

1. Defining the problem
2. Five-Why's
3. Human errors myth or reality

Deviation Investigation

1. Deviation investigation defined
2. Asking the right questions
3. Previous related investigations
4. Distinctions
5. Walk Through Analysis
6. Change Analysis
7. Control Barrier Analysis
8. Research assignments
9. Product impact
10. Deviations and validation data

Root Cause Analysis

1. Fishbone Diagram
2. Identify, eliminate, and prioritize root causes
3. Root cause options

Corrective Actions

1. Defined
2. Design space versus specifications
3. Solution identification

Preventive Actions

1. Defined
2. Solution identification
3. Decision Making Matrix.

Risk Analysis

1. What is acceptable risk?
2. Assessing risk
3. Simple risk assessment
4. Failure Mode and Effects Analysis
5. Managing the risks of a corrective and preventive action

Metrics

1. Measuring corrective action and preventive action success
2. Assuring follow-up success
3. Setting follow limits

This class is always customized to reflect your company's terminology around deviation investigations. Call us to discuss your needs.

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