

Root Cause Analysis for Better Investigations

Introduction and Overview

- ◆ Purpose
- ◆ What Has the FDA Said
- ◆ 6-Step Investigation Process

Step 1: Define Deviation Statement

- ◆ What Is A Problem
- ◆ Define Problem
- ◆ 5-Why's
- ◆ 5-Why's Example
- ◆ Data Gathering Questions
- ◆ Examples

Step 2: Deviation Investigation

- ◆ What Is Deviation Clarification
- ◆ Question Structure
- ◆ Questions
- ◆ Is, Is Not But Could Be
- ◆ Distinctions

Step 3: Root Cause Analysis

- ◆ Possible Root Causes
- ◆ Related Product Lots
- ◆ Downstream Materials
- ◆ Like Equipment
- ◆ Brainstorm Example

Step 4: Corrective and Preventive Action

- ◆ Corrective Action: Definition
- ◆ Corrective Action Checklist
- ◆ Corrective Action Example
- ◆ Preventive Action Definition
- ◆ Preventive Action Guidelines
- ◆ Preventive Action Examples
- ◆ Preventive Action Suitability Assessment

Step 5: Risk Assessment

- ◆ Risk Assessment Steps
- ◆ Simple Risk Assessment Steps
- ◆ Example

Step 6: Implementation, Monitor, Follow-up

- ◆ Task Planning
- ◆ Follow Up
- ◆ 6-Step Investigation Process

Course Length: 32 Minutes includes time to take the final exam.

Times are estimates and vary depending on the speed of taking the course assessments. Quiz questions are presented twice, once for the practice quiz and once for the final exam. Quiz times are estimated at 0.75 minutes for each question. Individual student response times may vary.

Who should take this class? New employees or those who need a new look at a deviation investigation model. This program is also a valuable review for someone about to conduct a deviation investigation. This is a great course as a part of a preventive action.

To purchase this program visit our on line shopping cart at:

<http://gallery.bcentral.com/GID5138385DD496508-CBT-Modules.aspx>

or,

Call: (415) 487-3500 to speak to a training consultant.