

# Effective Root Cause Analysis and CAPA Investigations for the Life Sciences

A Virtual Workshop Presented by WCG FDANEWS and ValSource Learning Solutions  
Tuesday, October 12, 2021 - Thursday, October 14, 2021 • 11:00 AM - 4:00 PM EDT

## Day 1

Tuesday, October 12, 2021

### 11:00 AM Effective Root Cause Analysis and CAPA Investigations for the Life Sciences-Day 1

11:00 AM – 3:30 PM EDT

- Why Investigate?
- Definitions and Models
- 14 Steps to Better Investigations

### 11:01 AM Welcome and Agenda for the Day

11:01 AM - 10:10 AM EDT

### 11:10 AM Why Investigate?

11:10 AM - 12:15 PM EDT

- Activity: Reasons for and benefits of investigations
- Patient safety
- Quality reasons
- Business reasons
- Investigations, Q10, and process understanding
- Regulatory expectations
- Regulatory agency findings, FDA observations, and Warning Letters

### 12:15 AM Break

12:15 PM - 12:45 PM EDT

**12:45 PM**    **Definitions and Models**

12:45 PM - 2:00 PM EDT

- Activity: Important definitions
- Six accident models: The value of models and how they can be used in investigations
- What about “human error”?
- Applying risk-based thinking to investigations, part 1

**2:00 PM**    **Break**

2:00 PM - 2:30 PM EDT

**2:30 PM**    **14 Steps to Better Investigations**

2:30 PM - 3:15 PM EDT

- The big picture
- Worksheets and data collection
- Activity: Making the case for an investigation team
- The investigation plan
- The importance of the “golden hours”

**3:15 PM**    **Summary/Wrap Up for the Day**

3:15 PM - 3:30 PM EDT

## Day 2

Wednesday, October 13, 2021

### 11:00 AM **Effective Root Cause Analysis and CAPA Investigations for the Life Sciences-Day 2**

11:00 AM – 3:30 PM EDT

- Conducting the Investigation: Tools to Help Identify the Causes and Contributors
- Interviewing Skills
- Working with subject matter experts
- What if You Can't Find the Root Cause?

### 11:01 AM **Welcome and Agenda for the Day**

11:01 AM – 11:10 AM EDT

### 11:10 AM **Conducting the Investigation: Tools to Help Identify the Causes and Contributors**

11:10 AM – 12:15 PM EDT

- Flow charting, process mapping
- Fishbone/cause-effect diagrams
- Fault trees
- Effect diagrams
- Timelines/chronologies
- Five whys
- Visualizations — Activity: Developing observational skills
- Change analysis
- Events and causal factors charting and analysis
- Activity: Small group work — How would you approach this situation?

### 12:15 PM **Break**

12:15 PM – 12:45 PM EDT

**12:45 PM Interviewing Skills**

12:45 PM – 1:25 PM EDT

- What makes for a good interview?
- The difference between an interview and an interrogation
- Triangulation
- How the brain works: The problem with re-telling and re-telling the story
- Activity: Role play on interviews

**1:25 PM Working with subject matter experts**

1:25 PM – 2:00 PM EDT

- Working with subject matter experts
- How experts “do it” C intuition and analysis
- Caveats when working with experts: biases that we all have
- Activity: Factors that can affect intuition

**2:00 PM Break**

2:00 PM – 2:30 PM EDT

**2:30 PM What if You Can't Find the Root Cause?**

2:30 PM – 3:15 PM EDT

- Demonstrating diligence
- The known/unknown matrix worksheet
- Increasing detection and protection to reduce risk

**3:15 PM Summary/Wrap Up for the Day**

3:15 PM – 3:30 PM EDT

## Day 3

Thursday, October 14, 2021

### 11:00 AM **Effective Root Cause Analysis and CAPA Investigations for the Life Sciences-Day 3**

11:00 AM – 3:30 PM EDT

- Assessing and Managing Risks Related to Investigations
- Corrections and Corrective Actions (and Preventive Actions)
- Writing it Up: Key Elements in a Report
- Your investigation system: what will you take back and do differently?

### 11:01 AM **Welcome and Agenda for the Day**

11:01 AM – 11:10 AM EDT

- Activity: Review of Day Two

### 11:10 AM **Assessing and Managing Risks Related to Investigations**

11:10 AM – 12:15 PM EDT

- Key definitions
- The risk management process
- Formulating the risk question
- Tools for assessing risk
- Using RA/RM in the investigation process

### 12:15 PM **Break**

12:15 PM – 12:45 PM EDT

### 12:45 PM **Corrections and Corrective Actions (and Preventive Actions)**

12:45 PM – 1:25 PM EDT

- How they differ, what they include
- Think Swiss cheese!
- Actions that add/don't add value
- Actions to consider when "human error" is involved
- Activity: What would you do? Finding new solutions

**1:25 PM Writing it Up: Key Elements in a Report**

1:25 PM – 2:00 PM EDT

- Writing it Up: Key Elements in a Report
- Activity: Four groups who read reports — and what they want to know
- How much? How long?
- What to include
- One purpose of the report: reducing fear, reducing risk
- Applying critical thinking concepts to a report — issue, conclusion, evidence
- Strengthening the report with evidence

**2:00 PM Break**

2:00 PM – 2:30 PM EDT

**2:30 PM Your investigation system: what will you take back and do differently?**

2:30 PM – 3:15 PM EDT

- Activity: Small group discussions and idea sharing

**3:15 PM Summary/Wrap Up for the Day**

3:15 PM – 3:30 PM EDT