

Conducting Advanced Root Cause Analysis and CAPA Investigations

Nov. 14-15, 2018 • Princeton, NJ
The Westin Princeton at
Forrestal Village

CRITICAL THINKING SKILLS AND INNOVATIVE TECHNIQUES TO IMPROVE INSPECTIONS

AGENDA

DAY 1

8:00 a.m. – 8:30 a.m. Registration/Continental Breakfast

8:30 a.m. – 10:00 a.m. **Welcome, introductions, and agenda**

Why investigate?

- *Interactive 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

10:00 a.m. – 10:15 a.m. Break

10:15 a.m. – 12:00 p.m. Definitions and models

- *Interactive 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

13 steps to better investigations

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

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:30 p.m. **After-lunch energizer**

Conducting the investigation: tools to help identify the causes and contributors

- Flow charting, process mapping
- Fishbone / cause-effect diagrams

- Fault trees
- Effect diagrams
- Timelines/chronologies
- Five whys
- Visualizations
- Change analysis
- *Interactive activity: Small group work—Your experiences with the tools*

Interviewing skills

- What makes for a good interview?
- Triangulation
- *Interactive activity: Interviewing*

2:30 p.m. – 2:45 p.m.

Break

2:45 p.m. – 4:45 p.m.

Working with subject matter experts

- How experts “do it” – intuition and analysis
- Caveats when working with experts
- *Interactive activity: Factors that can affect intuition*

What if you can’t find the root cause?

- Demonstrating diligence
- The known/unknown matrix worksheet

Putting it together: creating an investigation plan

- *Interactive activity: Writing an investigation plan for incidents.*

4:45 p.m.

Summary/Wrap up for the day

DAY 2

8:00 a.m. – 8:30 a.m.

Registration/Continental Breakfast

8:30 a.m. – 10:00 a.m.

Welcome and agenda for the day

Interactive activity: Review of Day 1

Where we were, where we are, where we’re going

Interactive activity: Four groups who read reports – and what they want to know

Assessing and managing risks related to investigations

- Key definitions
- The risk management process
- Formulating the risk question

- Tools for assessing risk
- Using RA/RM in the investigation process

10:00 a.m. – 10:15 a.m.

Break

10:15 a.m. – 12:00 p.m.

Corrections and corrective actions (and preventive actions)

- How they differ, what they include
- Think Swiss cheese!
- Actions that add/don't add value
- Actions to consider when "human error" is involved

12:00 p.m. – 1:00 p.m.

Interactive activity: What would you do? Finding new solutions

Lunch

1:00 p.m. – 2:30 p.m.

After-lunch energizer

Writing it up: key elements in a report

- How much? How long?
- What to include
- One purpose of the report: reducing fear

"Writing comes easier when you have something to say"

- Suggestions and hints for better reports
- Critical thinking and writing

2:30 p.m. – 2:45 p.m.

Interactive activity: Finding the good (and the bad) in a sample report

Break

2:45 p.m. – 4:00 p.m.

Interactive activity: Re-write! How would you write it?

Your investigation system: what will you take back and do differently?

- *Interactive activity: small group discussions and idea sharing*

4:00 p.m.

Summary/Wrap-up