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

*Interactive activity: What would you do? Finding new solutions*

12:00 p.m. – 1:00 p.m.  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

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

2:30 p.m. – 2:45 p.m.  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