BETTER INVESTIGATIONS, BETTER CORRECTIVE ACTIONS: Ways to conduct more effective root cause investigations

(Suggested course time: Day one – 8:30 to 16:30; Day two 8:30-16:00)

Course goal
Develop the skills and techniques to conduct more effective investigations of quality incidents and identify ways to reduce the likelihood of recurrence.

Course description
Problems like deviations and failures are a fact of life but individuals and organizations that understand what happened and why are in a much stronger position to establish corrective actions to reduce the likelihood that the event happening again.

This two-day workshop examines a defined, logical process that can be applied to investigations that are performed in the drug, biotech, and medical device industries. Tools like data collection sheets, checklists, and interview worksheets, based on some of the best practices in the pharma industry and beyond, and provided and used. A variety of problem solving, interviewing, and data collection techniques will also be examined.

"Human error" will be discussed along with ways to more fully understand what really caused or contributed to the incident and how those factors can be effectively addressed.

Participants will also have the opportunity to see the importance of a team approach when doing an investigation. Teams will review and critique an investigation report and discuss risk-based alternatives when a definitive root cause cannot be determined.

Who should attend
Those who conduct, review, or approve investigations in development, quality assurance, laboratories, operations, technical services, and maintenance/engineering.

Course objectives
- Discuss the expectations that GMP regulatory authorities have of investigations, CAPAs, and investigation reports.
- Differentiate between six different accident/incident models and how they can be applied during an investigation.
- Differentiate between root cause, contributing cause, and proximal cause.
- Discuss why human error is not a valid root cause.
- Given an incident, develop an investigation plan.
- Discuss the relationship between root, contributing, and proximal causes to corrections and corrective actions.
- Discuss a model that can be used to illustrate multiple layers of control and mitigation.
- Using a guideline, evaluate an interview.
- Identify four different audiences of investigation reports and what each is expecting to see in an investigation report.
- Discuss options of what can be done when a definitive root cause cannot be identified.

- Given an investigation report with deficiencies, identify ways to improve the report.

Course outline

DAY ONE

Welcome, introductions, and agenda

1. Why investigate?
- *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

2. Definitions and models
- *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

3. 14 steps to better investigations
- The big picture
- Worksheets and data collection
- *Activity: Making the case for an investigation team*
- The investigation plan
- The importance of the "golden hours"

4. 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
- *Activity: Small group work—Your experiences with the tools*

5. Interviewing skills
- 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: Critiquing an interview*

6. Working with subject matter experts

- How experts "do it" – intuition and analysis
- Caveats when working with experts
- *Activity: factors that can affect intuition*

7. What if you can't find the root cause?

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

8. Putting it together: creating an investigation plan

- *Activity: Writing an investigation plan for incidents.*

Summary/wrap up for the day

DAY TWO

Welcome and agenda for the day

Activity: Review of Day 1

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

9. 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. 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
- *Activity: What would you do? Finding new solutions*

11 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

12. "Writing comes easier when you have something to say"

- Suggestions and hints for better reports
- Critical thinking and writing
- *Activity: Finding the good (and the bad) in a sample report*

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

- *Activity: small group discussions and idea sharing*

14. Summary/wrap-up

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