

CONDUCTING ADVANCED ROOT CAUSE ANALYSIS AND CAPA INVESTIGATIONS

Understanding Advanced Critical Thinking Skills and Innovative
Techniques to Improve the Quality of Investigations

AN INTERACTIVE WORKSHOP PRESENTED BY LEARNINGPLUS LLC AND FDANEWS

YOUR EXPERT
SPEAKER:



James Vesper, PhD, MPH
President
LearningPlus, Inc.

This conference
has been pre-
approved by
RAPS as eligible
for up to 12
credits towards
a participant's
RAC
recertification.

SEPT. 16-17, 2015

HYATT HOUSE RALEIGH NORTH HILLS • RALEIGH, NC

DEC. 1-2, 2015

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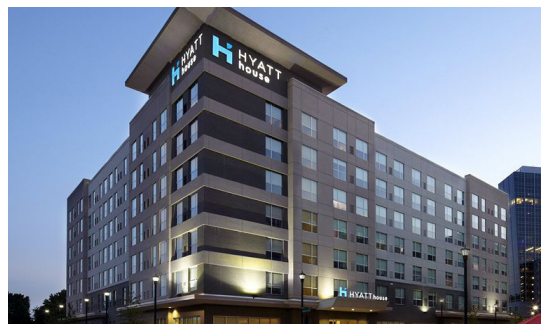
In this year's Conducting Advanced Root Cause Analysis
and CAPA Investigations workshop, you will:

- Learn how to conduct an effective, efficient investigation to avoid regulatory action and get a favorable closeout letter.
- Discuss lessons learned from recent FDA Warning Letter citations on CAPA investigations.
- Learn key problem-solving techniques to break a problem down into its component parts: Change Analysis, Fishbone Diagrams and Fault Trees.
- Receive a course workbook complete with charts, forms, manuals and guidance.
- Interact with colleagues during 12 interactive activities.

*"[James] is well informed
and has the ability to keep
the staff engaged."*

– Michael Witter, Processing Trainer,
Musculoskeletal Transplant Foundation

Inadequate investigations
and CAPAs have been the #1
reason for 483 observations
since 1997!



“I liked James’ training style. As a visual learner, he gave excellent examples to back up what he was explaining. Which helped me grasp a better understanding.”

– Lawanda Washington, RA/QA Manager, DSRV, Inc.

“Jim is an excellent presenter.”

– Ronay LeBlanc, Sr. Quality Specialist, UCB

WORKSHOP AGENDA

DAY ONE

8:30 a.m. - 10:00 a.m.

Welcome, introductions, and agenda

9:00 a.m. - 9:45 a.m.

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.**

Summary/wrap up for the day

DAY TWO

8:30 a.m. - 10:00 a.m.

Welcome and agenda for the day

- **Interactive activity: Review of Day 1**

Were 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

CAUSE ANALYSIS AND CAPA INVESTIGATIONS

TOOLS AND INNOVATIVE TECHNIQUES TO IMPROVE THE QUALITY OF INVESTIGATIONS



JAMES VESPER, PhD, MPH designs and develops instructional courses and workshops for pharmaceutical and medical device companies. He established and is president of the firm LearningPlus, Inc., and has had more than 30 years' experience in the pharmaceutical industry.

Mr. Vesper worked eleven years at Eli Lilly and Co. His first assignment was as corporate industrial hygienist, followed by three years in corporate quality assurance. He was responsible for issues concerning the manufacturing and testing of parenteral products made at Eli Lilly facilities and third parties worldwide. His last assignment at Lilly was project leader of GMP education and instruction, establishing the department and its mission.

COURSE BINDER MATERIALS:

- Copies of the presentation
- Forms and tables used in risk assessments
- Current FDA regulations
- Pertinent guidance documents
- FDA inspection manuals
- FDA's out-of-specification guidance
- ICH E6 good clinical practice guidance
- Recent citations from FDA Form 483s or EIRs
- Pertinent FDA warning letters
- Sample investigation plan
- FDA recall guidance
- Fishbone cause and effect diagrams
- Tips on documenting/presenting root causes
- Preventive action flowchart
- Investigation data collection worksheet
- Known/unknown worksheet
- CAPA checklist
- Mock failure investigation reports
- Key chapters on investigations from **GMP in Practice** by James L. Vesper
- And much more...

- 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**

Summary/wrap-up

"[James is a] Vault of knowledge that can be constructed to fit your company."

– Natalie Segro, Training Coordinator, Nice-Pak/PDI

CONDUCTING ADVANCED ROOT CAUSE ANALYSIS AND CAPA INVESTIGATIONS

Yes! Sign me up for the **Conducting Advanced Root Cause Analysis and CAPA Investigations**

	Complete Conference	Subtotal
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Name Title Phone E-mail	<i>Call for Discounts</i>	
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PAYMENT OPTIONS:

Check Enclosed: payable in U.S. funds to FDAnews
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HOTEL INFORMATION INFORMATION

Sept. 16-17, 2015
HYATT House Raleigh North Hills
 160 Park at North Hills Street
 Raleigh, NC 27609
 Toll Free: (888) 591-1234 • +1 (919) 363-0771
www.raleighnorthhills.house.hyatt.com
 Room rate: \$149.00 plus 12.75% tax
 Reservation cut-off: Aug. 25, 2015

Dec. 1-2, 2015
Tampa Marriott Waterside Hotel and Marina
 700 South Florida Avenue
 Tampa, FL 33602
 Toll free: (888) 268-1616 • +1 (813) 221-4900
www.TampaMarriottWaterside.com
 Room rate: \$169.00 plus 12% tax
 Reservation cut-off: Nov. 2, 2015

TEAM DISCOUNTS

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Multi-attendee discounts are available and will be calculated at check out.

- 2-4 attendees – 10%
- 5-6 attendees – 15%
- 7-9 attendees – 20%
- 10+ attendees – 25%

WORKSHOP TUITION

Tuition includes all workshop presentations, materials, two breakfasts, two luncheons, and refreshments.

CANCELLATION AND SUBSTITUTION

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund — less a \$200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.