FDANEWS PRESENTS THE

Multi-attendee discounts are available!

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.

"Dr. Vesper is very kind, has tremendous knowledge and experience. I learned so much about CAPA investigations and the tools that will help improve our quality system. Thank you!"

– China Trang, Sr. Manager of RA & QS, ZO Skin Health, Inc.

OCT. 13-14, 2016

AMA EXECUTIVE CONFERENCE CENTER
ARLINGTON, VA (WASHINGTON, DC)

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.

"This is a very well organized and informative course and I would recommend it to anyone who works with GMP."

– Erin Molnar, Sr. Quality Assurance Auditor, INC Research

Inadequate investigations and CAPAs have been one of the top reasons for 483 observations since 1997!

"[James Vesper is] Very engaging! Great knowledge of topic, excellent facilitation and with solid material experience. I like being able to discuss very specific issues we are facing in our job at the workshop."

– Christine Buccione, Sr. Quality Designer, Canadian Blood Services

"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 contrubutors

- 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

LS 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.

- 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

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...

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

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VENUE INFORMATION INFORMATION

Oct. 13-14, 2016
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2345 Crystal Drive, 2nd floor
Arlington, Virginia 22202
Tel: +1 (571) 481-2200
www.amaconferencecenter.org/washington.htm

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.