An Interactive Workshop Presented by Compliance Media, Inc. and FDAnews

CAPA has been the #1 reason for 483 observations since 1997!

Dec. 3-4, 2014 • Tampa Marriott Waterside Hotel and Marina
Tampa, FL

Conducting ADVANCED Root Cause Analysis and CAPA Investigations

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

In the Conducting ADVANCED Root Cause Analysis and CAPA Investigations workshop, you will:

- Get an insider view of the FDA's own training program for investigators — portions of the Reid Technique DVD will be reviewed during the course
- Review lessons learned from more than 15 years of FDA warning letter citations on investigations and CAPA
- Learn key problem-solving techniques to break down a problem into its component parts
- Interact with colleagues to participate in 8 advanced, interactive exercises
- Leave this workshop better able to conduct CAPA investigations

Gregory Meyer RAC, CQA
President and Principal Consultant and Trainer
Compliance Media, Inc.

Visit www.CAPAworkshop.com or call (888) 838-5578

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Conducting ADVANCED Root Cause

Understanding Advanced Critical Thinking Skills and Inno

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"I loved this course. [I] learned so much and the take home materials are great and can be used to train employees. I will highly recommend this course to others."

— Kate Garrido, Millennium Pharmaceuticals

"Very good examples to help me understand CAPA."

– David Flemming, QA Manager, Bionique Testing Laboratories

WORKSHOP AGENDA

DAY ONE

8:00 A.M. – 8:30 A.M. REGISTRATION/ CONTINENTAL BREAKFAST

8:30 a.m. – 10:00 a.m. FDA Regulatory Requirements and Enforcement

- Patient safety is our number-one concern
- Review of FDA requirements
- Corrective and preventive action terms
- Recent FDA inspection and enforcement trends
- Required FDA notifications
- **Interactive Exercise!** What's Driving Us Crazy?

10:00 A.M. – 10:15 A.M. BREAK

10:15 a.m. – 12:00 p.m. Problem Solving and Investigations

- Identifying and reporting problems quickly
- Initial risk assessment
- Determining need for an investigation
- Problem statements and key steps
- Six solution criteria
- Creative-problem solving techniques
- **Interactive Exercise!** Analyze cases and determine risks and need for an investigation; draft investigation plan if needed

12:00 P.M. – 1:00 P.M. LUNCH

1:00 p.m. – 2:30 p.m. Root Cause Analysis Tools and Techniques

- Brief review of common tools: Ishikawa diagram, flow charts, 5 whys, Is/Is not, cause and effect charts
- Root cause analysis process
- Tips on determining root causes and probable root causes
- Data visualization techniques
- Collaborative analysis
- **Interactive Exercise!** Brainstorm root causes for real cases with peers

2:30 P.M. – 2:45 P.M. BREAK

2:45 p.m. – 4:45 p.m. Interviewing and Writing

- Interviewing techniques
- Writing truths and tips
- Critical thinking in a nutshell
- Review portions of audiovisual program FDA uses to train its investigators on interviewing employees and management
- **Interactive Exercise!** Practice identifying problem statement
  Interactive Exercise! Practice interviewing a peer

4:45 p.m. – 5:00 p.m. Lightning Round
Evening Work
Compliance Program Guidance Manual and Warning Letter

DAY TWO

8:00 A.M. – 8:30 A.M. REGISTRATION/ CONTINENTAL BREAKFAST

8:30 a.m. – 10:00 a.m. Best Practices

- Discussion of insights from evening assignment
- Brief review of investigation tips and techniques used by other industries
- Discussion on data sources, root cause determination, effectiveness checks, timeliness, computerized systems and other critical issues
- **Interactive Exercise!** Best practices exercise in small groups

e Analysis and CAPA Investigations

vative Techniques to Improve the Quality of Investigations

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YOUR EXPERT INSTRUCTOR

Gregory Meyer RAC, CQA is President and Principal Consultant and Trainer at Compliance Media, Inc. Mr. Meyer has been providing quality assurance, quality systems, and clinical regulatory guidance for biopharma and medical device companies for more than 20 years. He has conducted training for industry, regulators and academia and regularly presents at meetings of the Parenteral Drug Association, the American Society for Quality, and the Regulatory Affairs Professionals Society. He has held director level positions in biopharma, small molecule and medical device companies in quality, regulatory affairs, and compliance. His training production company, Compliance Media produced the video documentary FDA: A History for the U.S. Food and Drug Administration's Centennial in 2006 and he is a recognized expert in the history and operations of FDA, as well as ICH Guidance, ISO compliance, and GHTF standards for medical devices.

10:00 A.M. – 10:15 A.M. BREAK

10:15 a.m. – 12:00 p.m. Critical-Thinking and Decision-Making

- Key elements of critical thinking
- Avoiding analytical traps
- Logic, argument and risk assessment
- Considerations in making good decisions
- Preparing to defend your thinking and recommendations
- **Interactive Exercise!** Practice using critical-thinking skills with peers on a case

12:00 P.M. – 1:00 P.M. LUNCH

1:00 p.m. – 2:30 p.m. Advanced Writing and Corrective and Preventive Action

- Detailed suggestions for crafting and writing reports and summaries. Writing is "thinking on paper," as revered writer and teacher William Zinsser says
- Correcting detected problems
- Preventing problems from occurring, including at other sites
- Bullet-proofing your work
- Communication to all affected sites or suppliers
- **Interactive Exercise!** Review cases and develop possible corrective and preventive actions

2:30 P.M. – 2:45 P.M. BREAK

2:45 p.m. – 4:45 p.m. Major Case Development

- Determining risk and urgency of problem
- Determining if an investigation is needed
- Using flow chart to understand the manufacturing, clinical, QA/QC, or other process involved
- Identifying possible root causes and documenting them
- Developing possible corrective and preventive actions, and effectiveness checks for each
- **Interactive Exercise!** Discuss selected case and present findings and recommendations to class

4:45 p.m. – 5:00 p.m. Review and Key Insights

YOUR COURSE MATERIALS

Each participant will receive a folder and flash drive packed with tools and reference materials in a combination of both electronic and hard copy format you can put to use right away, including:

- Copies of the presentations
- How to respond to FDA Form 483s
- and warning letters
- Comprehensive CAPA bibliography
- and recommended reading list
- Current FDA regulations
- Pertinent guidance documents
- Three articles on problem
- investigations
- FDA inspection manuals
- FDA's out-of-specification guidance
- ICH E6 good clinical practice guidance
- Recent FDA Form 483s or EIRs
- Pertinent FDA warning letters
- 16 great interviewing tips
- Two articles on CAPA
- FDA recall guidance
- Writing an executive summary
- Fishbone cause and effect diagrams
- Risk matrix chart
- Tips on documenting/presenting root causes
- Preventive action flowchart
- Author's questionnaire
- CAPA checklist
- Mock failure investigation reports
- Sample investigation plan
- Sample case review form
- Tips on conducting out-of-specification
- investigations
- Compliance tips/best practices
- Problem-solving worksheet
- Corrective action process checklist
- And much more...

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LOCATIONS AND HOTEL ACCOMODATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **FDAnews** workshop to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. The hotel may require the first night's room deposit with tax. Room cancellations within 72 hours of the date of arrival or "no-shows" will be charged for the first night's room with tax.

LODGING AND CONFERENCE VENUE:

Dec. 3-4, 2014
Tampa Marriott Waterside Hotel and Marina
700 South Florida Ave.
Tampa, FL 33602
Toll Free: (888) 268-1616
+1 (813) 221-4900
www.TampaMarriottWaterside.com
Room rate: $169.00 plus 12 percent tax
Reservation cut-off date: Nov. 11, 2014

TUITION

Tuition rate is $1,897 per person and includes all workshop sessions, workshop materials, two breakfasts, two luncheons and daily refreshments.

CANCELLATIONS AND SUBSTITUTIONS

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 of 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.

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. Call (888) 838-5578 for details.

FOUR EASY WAYS TO REGISTER

Online: www.CAPAworkshop.com
Fax: +1 (703) 538-7676
Phone: Toll free (888) 838-5578 (inside the U.S.)
or +1 (703) 538-7600
Mail: **FDAnews,** 300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 USA

☑ **YES!** I want to attend **Conducting ADVANCED Root Cause Analysis and CAPA Investigations**

I understand the fee of $1,897 includes all workshop sessions, workshop materials, two breakfasts, two luncheons and daily refreshments.

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300 N. Washington St., Suite 200
Falls Church, VA 22046-3431

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(Please see "Team Discounts" above for tuition discounts when you send a team of three or more.)

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