FDANEWS PRESENTS

Multi-attendee discounts are available!

CONDUCTING INTERNAL GMP/QSR/GCP/GLP INVESTIGATIONS

How to Avoid Sleepless Nights, Irreparable Harm to Your Company's Reputation, and Massive Civil and Criminal Liability

AN INTERACTIVE WORKSHOP PRESENTED BY ALSTON & BIRD LLC AND FDANEWS

YOUR EXPERT INSTRUCTORS:

CATHY BURGESS
Partner
Health Care Group

EDWARD (TED) KANG
Partner
Government & Internal Investigations

MARK CALLOWAY
Partner
Government & Internal Investigations

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

APRIL 22-23, 2015 ALSTON & BIRD LAW OFFICES, WASHINGTON, DC

Come to Washington, DC for a two-day crash course in how to conduct internal investigations related to possible GMP, QSR, GCP or GLP data integrity and whistleblower related violations. You'll come home toting a bagful of tricks and tips to improve your internal processes, strengthen your compliance systems and avoid lawsuits – even possible jail time.

Taught by three accomplished clinical, manufacturing, laboratory and white-collar crime attorneys — who have more than 50 years of experience conducting investigations, this event is like no other on the market. Get ready to discover:

- **How to assess initial allegation(s)** While each investigation is unique, you'll learn guidelines that help you respond swiftly and appropriately to whistleblower complaints.
- **Practical and actionable first steps** These include:
  - Identifying scope and purpose of the investigation
  - Structuring the investigative team of internal employees, outside counsel and subject-matter experts
  - Maintaining credibility of the investigation and protecting attorney-client privilege
  - Best practices in document preservation and review, done cost-effectively but ready to withstand regulators' tightest scrutiny
  - Tips on interviewing employees drawn from 50 years of collective experience and hundreds of actual interviews
- **The 'Park Doctrine'** Prosecutions under the so-called "Park Doctrine" are a growing threat. The "Park Doctrine" mirrors a recent Justice Dept. policy shift to changing corporate misbehavior by holding officers and employees individually accountable.
- **Changing corporate culture** You'll learn all about the "responsible corporate officer" … how one can be held liable for violations of the FDCA with no criminal intent … and how to avoid such prosecutions by cultivating a corporate culture that puts quality first.
- **As the workshop winds up** You'll come away with a deepened understanding of how to conduct internal investigations, plus mitigation strategies to avoid the sort of GMP/QSR/GCP/GLP problems that have cost others millions of dollars in civil – and criminal – penalties.

DAY ONE | APRIL 22

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. - 9:30 a.m.

Whistleblower Allegations in a GMP/QSR/GCP/GLP Environment

- Hotline calls and other complaints
- Purpose of internal investigations

9:30 a.m. - 10:15 a.m.

Overview of Whistleblower Protections/Increased Government Oversight of Corporate Conduct

10:15 a.m. - 10:30 a.m.

Break

10:30 a.m. - 12:00 p.m.

Do We Investigate?

- When is an internal investigation required? When is it discretionary?
  - Investigations mandated by regulation, statute, or corporate policies
  - Whistleblower complaints and whistleblower credibility
  - Risk assessments when investigation is not mandatory
- Who should run the investigation?
  - Internal versus outside counsel
  - Determining the role of senior executives, audit committees, board of directors, etc.
  - Considering conflicts of interest when staffing investigations
  - Clarifying the terms of engagement and appropriate role of outside counsel

Exercise — Evaluation of Hotline Complaint and Recommendations for Next Steps

12:00 p.m. – 1:00 p.m.

Lunch

1:00 p.m. - 2:30 p.m.

What Is Our Plan?

- Identifying issues and objectives
- Determining appropriate scope
- Budgeting for an internal investigation
- Considering how corporate policies and procedures should impact the investigation (e.g. corporate privacy policies, etc.)
- Engaging third-party vendors and forensic specialists
- Special considerations for multinational investigations
- Strategic plan for managing internal messaging regarding the investigation
- Strategic plan for managing external messaging, including public disclosures and responses to media inquiries
- Protecting the privilege through an internal investigation

Exercise — Developing the Investigation Plan

2:30 p.m. - 2:45 p.m.

Break

2:45 p.m. – 4:30 p.m.

Conducting the Internal Investigation

- Document collection and review
  - Litigation hold notices
  - Custodian interviews and identifying potential sources of documents
  - Defining the scope of document collection
  - Methods of document collection
  - Document review process and considerations
- Conducting witness interviews
  - Deciding who to interview
  - Planning and preparing for the interview
  - The Upjohn warning
  - Tips and tricks for conducting the interview
  - The challenging interview: dealing with reluctant, hostile, and lying witnesses
  - Memorializing the interview and determining next steps
- Documenting the investigation, providing internal updates, and taking interim action
  - Documenting the investigation and keeping key evidence organized
  - Written versus oral updates
  - Keeping senior management, the audit committee, or the board informed
  - Deciding whether and to what extent to take immediate corrective action, including disciplining or terminating employees

Exercise — Best Practices For Witness Interviews

4:30 p.m.

Adjourn Day One

Course Binder Materials:

- Copies of the presentations
- Current FDA regulations
- Tips on conducting internal investigations
- Article, “Recurring Issues in Internal Investigations”
- Guidances
- Case studies
- Checklists
- Sample litigation hold/preservation notice
- Dos and don’ts in conducting interviews of employees and witnesses in internal investigations
- How the DOJ Consumer Protection Branch conducts criminal investigations of the FDCA
- How the DOJ uses the Park Doctrine to hold officers, managers, and employees criminally liable for violations of the FDCA--no criminal intent required.
- And more…

P/QSR/GCP/GLP INVESTIGATIONS

DAY TWO | APRIL 23

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. - 10:30 a.m.

Individual Liability and the Park Doctrine

- The evolution of potential individual exposure during the course of an investigation
- What is the Park Doctrine?

Exercise — Case Studies Involving Application of the Park Doctrine

10:15 a.m. - 10:30 a.m.

Break

10:30 a.m. - 12:00 p.m.

We Know What Happened, Now What?

- Considering whether to create a final report and determining what to include
- Deciding whether and when to voluntarily disclose misconduct
- Taking disciplinary action
- Delivering results to senior management, the audit committee, or the board
- Anticipating backlash: preparing for increased government scrutiny, shareholder lawsuits, and media inquiries
- Preventing whistleblower retaliation

Exercise — Reports to Senior Management and Audit Committees

12:00 p.m. - 1:00 p.m.

Lunch

1:00 p.m. - 2:30 p.m.

Building a Culture of Compliance: It Starts at the Top

- Top down commitment to quality and compliance
- Risk assessment
- Developing and revisiting policies and procedures
- Employee training
- Document tracking
- Anonymous reporting
- Considerations in developing reporting chains

Exercise — Developing a Corrective Action Plan

2:30 p.m. - 2:45 p.m.

Break

2:45 p.m. - 4:00 p.m.

Exercise — Liability for GMP/QSR/GCP/GLP Violations (Case Studies)

4:00 p.m. - 4:30 p.m.

Wrap Up – Best Practices

4:30 p.m.

Adjourn Day 2

WHO WILL BENEFIT?

If your company manufactures drugs, devices, conducts clinical trials or runs laboratory operations – or if you serve such firms as a lawyer or contractor – this workshop is for you. Here are just a few of the many executives who can benefit:

- Executive management
- General/corporate counsel
- Manufacturing directors and supervisors
- Clinical directors and supervisors
- Laboratory directors and supervisors
- Internal compliance directors and supervisors
- Regulatory/legal affairs professionals
- Data management and statistics personnel
- Engineering and design controls teams
- Risk management specialists
- Audits and investigators
- QA/QC personnel
- R&D staff
- Training personnel
- Validation specialists, scientists, engineers
- Personnel new to the industry

YOUR EXPERT INSTRUCTORS:

Cathy Burgess is a partner in Alston & Bird's Health Care Group focusing on FDA matters. Ms. Burgess advises clients on matters affecting Rx and OTC drugs, biologics, medical devices, foods and cosmetics, working with clients to spot legal risks throughout product life cycles. With her cGMP expertise, she focuses on quality systems, adequacy of SOPs, investigation reports, inspection management, recalls, and responses to Forms 483 and Warning Letters.

Edward (Ted) Kang is a partner in Alston & Bird's Government & Internal Investigations Group. He focuses on white collar matters in the areas of health care, anti-corruption, Office of Foreign Assets Control (OFAC) sanctions, anti-money laundering, and the Foreign Corrupt Practices Act (FCPA). Clients include parties under investigation by the Justice Dept. and other federal and state enforcement agencies.

Mark Calloway, is a partner — and immediate past leader — of Alston & Bird's Government & Internal Investigations Group, specializes in white collar criminal defense with an emphasis on health care, internal corporate investigations, compliance program development, implementation and auditing. From 1994-2001 he served as U.S. Attorney for the Western District of North Carolina. He also served as director of the Executive Office for U.S. Attorneys in Washington DC.

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APRIL 22-23, 2015

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www.alston.com/washington_dc/

Hotel sleeping rooms have not been designated for this event. For your convenience, here is a list of hotels with distance from the venue:

- Courtyard Washington Convention Center – 1 block
- Hotel Monaco – 2 blocks
- Hotel Harrington – 2 blocks
- Grand Hyatt Washington – 3 blocks
- Washington Marriott at Metro Center – 4 blocks
- JW Marriott Washington DC – 4 blocks
- Intercontinental The Willard Washington DC – 4 blocks

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%

TUITION:

Tuition of $1,897 includes all workshop sessions, workshop written materials, two continental breakfasts, two luncheons and four networking and refreshment breaks.

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.