

AGENDA

Pre-Meeting Workshops – Monday, March 5, 2012

1:30-5pm **Being a Business Partner – Influence and Soft Skills for Compliance Professionals**
Presenters: Matthew Yesko, Steve Celestini, and Brian Lange
This workshop is designed for the compliance professional who wants to learn how they can specifically add value to the compliance function and be viewed as a trusted advisor and business partner. Participants will be able to:

- Create conditions where compliance is viewed as a trusted resource
- Apply specific skillset to positively influence stakeholders
- Develop the connection between business outcomes and compliance “rules”

1:30-5pm **Pharma Compliance 101 Workshop**
Presenters: Gary DelVecchio, Margaret Feltz and Kelly Freeman
Pharma Compliance 101 is an introduction to pharmaceutical compliance laws and concepts intended for new (or newer) pharma compliance professionals. The seminar will provide an opportunity to learn and share basic concepts, including practical approaches to implementing a compliance program. This pre-meeting workshop will help new people develop foundational knowledge and help them more fully engage in the meeting itself.

Topics covered:

- Overview of Pharma Compliance Programs
- Key Laws, Regulations, and Guidance: OIG Compliance Program Guidance for Pharmaceutical Manufacturers, Federal Sentencing Guidelines, PhRMA Code, FDA regulations and important settlements with the government.
- Implementing the seven elements of a compliance program: Practical advice and best practices for policy development, training, communications, monitoring, auditing, and corrective actions.
 - Sales and Marketing Compliance
 - Med Affairs and Clinical Compliance
 - International Compliance
- Interactive group discussion of hypothetical scenarios

Day 1 of Main Meeting – Tuesday, March 6, 2012

8-8:15am **Welcome and Antitrust Admonition**

8:15-9:15am **PhRMA Update** – Overview of the Consolidated Comments on the Draft Sunshine Act and Discussion of Draft FDA Regulations Regarding Off Label Questions
Speaker: A representative from PhRMA

9:15-10am **The Evolving Compliance Professional**
Presenters: Matthew Yesko, Steve Celestini, and Brian Lange
During their address, the group will learn more about:

- The rising importance of influence skills for compliance professionals
- The impact of “scaring an audience straight”
- Why “how we think of ourselves” matters to our stakeholders

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Day 1 of Main Meeting – Tuesday, March 6, 2012 (cont.)

10-10:30am **Refreshment Break**

10:30am-12pm **Update from the Feb 23, 2012 OIG Pharmaceutical Compliance Roundtable with Companies Operating under a CIA**

12-1:30pm **Lunch & Networking**

1:30-2:30pm **Discussion of New and Evolving CIA Requirements**
Speakers: Clive Davis from UCB and Mary Dimauro from Merck

2:30-3pm **Refreshment Break**

3-3:45pm **Recent Trends in Executive Liability: What do your Executives need to know about it?**
Speaker: Tom Gallagher, Pepper Hamilton LLP

3:45-5pm **Open Forum and Round Table Discussions**

5-6:30pm **SUPER NETWORKING RECEPTION**

This meeting we will be assembling backpacks full of food for the Inter-Faith Food Shuttle whose mission is to Drive Hunger from the Community. These backpacks will be provided to children who go to school and have lunch provided and this food allows them to get good nutrition on the weekends when meals are not provided. Make sure you come to the reception and eat, network and help fill a backpack full of food for a child in need.

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Day 2 of Main Meeting – Wednesday, March 7, 2012

7-8am **Breakfast**

8-9:15am **Breakout Sessions**

- Managed Markets
- Aggregate Spend
 Moderator: Deborah Penza from Watson Pharmaceuticals
- Research & Development
- Auditing & Monitoring

9:15-9:30am **Refreshment Break**

9:30-10:45am **Breakout Sessions**

- Social Media Uses and Policies
- Small Company
 Moderator: Beth Levine from Regeneron Pharmaceuticals
- FCPA Operational Issues and Metrics
- Canadian Compliance Issues
 Moderators: Derek Khan from Eli Lill
 Litsa Kouroumalis from Bristol-Myers Squibb

10:45-11am **Transition Break**

11-11:05am **Welcome and Antitrust Admonition**

11:05am-12pm **Open Forum and Round Table Discussions**

12-1pm **Lunch**

All meeting activities will take place at The Umstead Hotel:

THE UMSTEAD HOTEL

100 Woodland Pond Drive

Cary, NC 27513

Phone: 919-447-4000

<http://www.theumstead.com/>

To Download the Registration Form please click below:

<http://www.pharmacomplianceforum.org/docs/PCF2012SpringReg.pdf>