

2007 pharmaceutical internal auditing conference

mitigating risk through auditing and monitoring

sessions include:

- Pitfalls and Pathways in Prescription Drug Promotion
- Building a Corporate Compliance Audit Function – Lessons Learned
- Field Force Monitoring – Best Practices
- Practical Compliance under the Foreign Corrupt Practices Act

october 18 – 19, 2007

sheraton society hill hotel
philadelphia, pennsylvania

AHIA

7:30 AM–4:30 PM

Registration Open

7:30 AM–8:30 AM

Breakfast

8:30 AM–9:30 AM

Keynote Presentation: Pitfalls and Pathways in Prescription Drug Promotion

Paul Savidge, Vice President, Global Labeling & Promotion Compliance, Bristol-Myers Squibb

Learning Objectives:

1. Basic Elements of US Prescription Drug Advertising
2. How to Identify Common Pitfalls in Prescription Drug Advertising
3. Hot Issues in Prescription Drug Advertising
4. Roles and Responsibilities of the Promotion Review Team
5. An Approach to Auditing the Promotion Review Function

9:30 AM– 9:45 AM

Coffee break

9:45 AM–10:45 AM

State Level Compliance

David Vance, JD, MA, Sr. Director, Business Conduct, Gilead Sciences, Inc.
Kim Life, JD, MA, Associate Director, Business Conduct, Gilead Sciences, Inc.

Learning Objectives:

1. Current and new State reporting and disclosure requirements
2. State(s) requiring price disclosures
3. States requiring expense reports

4. State(s) requiring compliance programs

5. Other limitations or requirements

6. Related aggregate spend tracking issues

10:45 AM–11:00 AM

Refreshments

11:00 AM–12:00 PM

Brand Auditing and Strategy Planning

Raymond Furey, Senior Manager, Healthcare Compliance Audit, Genentech
Stephen Payne, Sidley Austin LLP

Learning Objectives:

1. Approach to conducting a brand audit
2. Areas of focus in clinical development and medical affairs
3. Conducting interviews and documentation requests
4. Client attorney privilege considerations
5. Developing a long-term audit plan

12:00 PM–1:00 PM

Networking Lunch

1:00 PM–2:00 PM

Medical Science Liaisons and Requests for Medical Information: Monitoring and Auditing to Mitigate Regulatory Risks

Ann Lewis, Vice President & Senior Counsel U S Healthcare Law Compliance, Bristol-Myers Squibb

Learning Objectives:

1. History and evolution of Medical Science Liaisons
2. Laws and regulations governing promotion and off-label information
3. Business processes and controls for providing medical information

4. Auditing and monitoring techniques for assessing compliance with laws and policies

5. Survey of trends and corporate integrity agreements with respect to the provision of medical information

2:00 PM–2:15 PM

Refreshments

2:15 PM–3:15 PM

Field Force Monitoring – Best Practices

Kelly Freeman, Director, Compliance and Ethics, US Affiliate, Eli Lilly and Company

Learning Objectives:

1. How to develop a sales force compliance monitoring program.
2. What types of activities should be monitored.
3. How monitoring is complementary to auditing.

3:15–3:30 PM

Refreshments

3:30 PM–4:30 PM

Grants and Supporting Educational Activities

Heather Stewart, Director, Corporate Compliance Counsel, MedImmune

Learning Objectives:

1. Increasing level of scrutiny on industry support of third party educational activities
2. Applicable legal and regulatory framework
3. Industry standards
4. Role of auditing and monitoring in mitigating risk in this area

6:00 PM–8:00 PM

Networking Dinner Reception

friday
schedule

Presented By
The Association of
Healthcare Internal Auditors



For more information about AHIA or to join, please contact us at:

AHIA
10200 W. 44th Avenue, Suite 304
Wheat Ridge, CO 80033
888-ASK-AHIA (275-2442)
(303) 327-7546
Fax: (303) 422-8894

www.ahia.org ahia@ahia.org

who should attend

- Individuals with audit experience who are new to the pharmaceutical industry
- Individuals with pharmaceutical industry experience but new to the audit profession
- Pharmaceutical internal auditors

general information

Hotel

Sheraton Society Hill Hotel
One Dock Street
Philadelphia, Pennsylvania 19106

Hotel Reservations: (800) 325-3535

Phone: (215) 238-6000 / Fax: (215) 238-6652

<http://www.starwoodmeeting.com/Book/AHIA2007/societyhill.sales@sheraton.com>

Enjoy a warm welcome and step back in time to colonial Philadelphia at the Sheraton Society Hill Hotel. While you are here, visit America's most historic square mile, which includes such sites as Independence Hall and the Liberty Bell, just four blocks away.

Reservations:

Go to the hotel's Conference web site at: <http://www.starwoodmeeting.com/Book/AHIA2007> or call the Sheraton Society Hill Hotel at (800) 778-7477 and request the Association of Healthcare Internal Auditors rate of \$209.00 plus tax (single/double) by September 22, 2007.

Please Note

- Rooms are blocked from October 18–19, 2007. The group rate will be honored three days before and after the conference, based on availability.
- Reservations must be made by Saturday, September 22, 2007 in order to receive the AHIA discounted room rate. However, please note that sleeping rooms

are assigned on a first-come, first-served basis and may sell out before September 22.

- The association has committed to a block of sleeping rooms for this event. If you make the decision to stay at another property, not only is it less convenient for you, but it also may harm the association financially. We encourage you to reserve your room at the headquarters hotel and support AHIA.

Important Dates

- September 22: Hotel reservation cutoff.
- September 24: Registrations submitted AFTER this date will be assessed an additional \$50.
- October 1: Cancellations must be received in writing by this date in order to receive a refund of registration fees minus \$50. No refunds will be given after this date.

Networking Dinner Reception

Thursday, October 18, 6:00 pm – 8:00 pm

Join us to get acquainted with other attendees, presenters, and pharmaceutical industry leaders during our Networking Dinner Reception from 6:00 pm – 8:00 pm. Socialize, converse, and enjoy the reception after a great day of educational sessions.

This event is included in your registration fee.

7:00 AM–11:30 AM

Registration Open

7:00 AM–8:00 AM

Breakfast

8:00 AM–9:00 AM

Keynote Presentation

Kathleen Meriwether, formerly of the U.S. Attorney's Office, will speak on the subject of health care fraud.

9:00 AM–9:15 AM

Coffee break

9:15 AM–10:15 PM

Building a Corporate Compliance Audit Function—Lessons Learned

Gary Simone, Senior Director, Corporate Compliance Audit, Bristol Myers Squibb

Learning Objectives:

1. Approaches to designing & building a compliance audit function
2. How to solicit and weigh feedback from a diverse client pool
3. The importance of clear, concise and consistent communication
4. Responding to clients with multiple agendas
5. Practical real-life lessons learned

10:15 AM–10:30 AM

Refreshments

10:30 AM–11:30AM

Harmonizing Regulatory Requirements: Sox and Commercial Practices

*Kathy Lorge, Consultant, Lorge and Associates
Deborah Frazer, Sr. Director, Internal Audit,
Gilead Sciences*

Learning Objectives:

1. Understand the impact of AS5 on pharmaceuticals.
2. Develop an understanding of the overlaps of SOX requirements with commercial practices compliance requirements.
3. Understand the impact of regulatory requirements on a risk-based Internal Audit approach.
4. Learn how to efficiently allocate Internal Audit resources for maximum coverage.

11:30 AM–12:30 PM

Networking Lunch

12:30 PM–1:30 PM

Practical Compliance under the Foreign Corrupt Practices Act

Jeff Hessekiel, Senior Director, Commercial Legal Affairs & Litigation, Gilead Sciences, Inc.

Learning Objectives:

1. The basic structure and expectations of the Foreign Corrupt Practices Act
2. Recent enforcement of the Act
3. Practical suggestions for how to achieve compliance with the Act

1:30 PM–1:45 PM

Refreshments

1:45 PM–2:45 PM

Monitoring and Auditing Relationships with Healthcare Professionals, Governance/Controls for Interactions

Keith Korenchuk, Attorney at Law, Covington & Burling LLP

Learning Objectives:

1. Identifying key issues to assess in healthcare professional relationships
2. Developing an effective approach for testing compliance with company policy

3. Creating a framework to facilitate evaluating, monitoring and auditing
4. Developing appropriate boundaries between internal audit and compliance

2:45 PM–3:00 PM

Refreshments

3:00 PM–4:00 PM

Pharmaceutical Internal Auditing: More than Sales and Marketing

Nancy Haig, MBA, CIA, CFE, CBA, CCSA, CFSA, CICA, Senior Director, Internal Audit, Eisai Corporation

Learning Objectives:

1. Risk assessment, enterprise risk management, and developing the audit plan
2. Working with Compliance, assessing the compliance program, and determining risks to audit

For expanded descriptions of each session and speaker biographies, go to <http://www.ahia.org/> and click on the conference registration link.

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Continuing Professional Education Credits

AHIA is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Suite 700, Nashville, TN, 37219-2417. Website: www.nasba.org. No prerequisite courses, advance preparation, or experience is required for admittance to the seminar. Pharmaceutical Internal Auditing Conference Available CPE Credits: 14.4

Speakers from the pharmaceutical industry, healthcare law and the auditing profession will present information on compliance, ethics, business processes, risk assessment and management as they are related to pharmaceutical auditing. This intermediate-level conference will be presented in a group-live format.



Registration

The AHIA registration cost includes training materials, presentation, networking reception, and breakfast, lunch and breaks for both days. **The preferred method for registration is the online secured registration form at www.ahia.org.**

Registrations will be accepted on the official registration form only. Photocopies of the form are acceptable. Acceptable methods of payment are check, money order, American Express, Discover, MasterCard, or VISA.

A confirmation of registration will be sent to you upon receipt of your paid registration. Registrations will be accepted on a first-come, first-served basis and the 2007 Pharmaceutical Auditing Conference may sell out at any time. Therefore, we highly encourage you to confirm your registration with AHIA before making travel arrangements.

Cancellation, Substitution and Refund Policy

Registration cancellations prior to September 24 will incur no penalty. Cancellations from September 24 to October 1 are subject to a \$50 cancellation fee. Cancellation notices must be sent in writing to the AHIA Executive Office. No refunds will be made on cancellations made after October 1 due to committed funds; forfeited fees cannot be applied to future meetings due to IRS reporting requirements.

Substitutions from within the same company are permitted at no additional cost if received by October 1. All substitutions must be in writing and accompanied by a completed registration form.

Transportation between the airport and hotel:

The recommended means of transportation between the airport and the Sheraton Society Hill Hotel is the airport shuttle, which is approximately \$10 one-way. Taxicabs are approximately \$26 and town cars are available for approximately \$60 one-way.

Philadelphia Travel Information

<http://www.philadelphiausa.travel/philadelphia.php>

Attire

Attire for this educational meeting is business casual. As with most events, the temperature in different meeting rooms tends to vary. We recommend that you dress in layers to accommodate the variance in temperatures.

Smoking

In consideration of others, we ask that you refrain from smoking during conference functions and throughout the conference area.

Americans with Disabilities Act

The Sheraton Society Hill Hotel complies with the provisions of ADA. If you need any additional assistance beyond what is accommodated by ADA, please contact AHIA by September 24 so that we may assist you.

Disclaimer

If AHIA cannot hold the 2007 Pharmaceutical Conference due to acts of God, war, government regulations, disaster, civil disorder or curtailment of transportation facilitating other emergencies making it inadvisable, illegal, or impossible to provide the facilities or to hold the meeting, each prepaid attendee will receive a copy of the conference handouts and any other materials that would have been distributed. Fixed conference expenses will be paid from the pre-registration funds. Remaining funds will be refunded to pre-registrants. AHIA is not responsible for any other costs incurred by pre-registrants in connection with the conference.

The views and opinions expressed by presenters are their own and do not necessarily represent those of AHIA. AHIA disclaims any responsibility for the use and application of information presented at this conference.

For more information regarding refund, complaint and program cancellation policies, please contact AHIA at 888-ASK-AHIA (275-2442).



10200 W. 44th Avenue
Suite 304
Wheat Ridge, CO 80033

register today!
deadline is
september 24, 2007.

registration form ahia pharmaceutical auditing conference, october 18-19, 2007

to register:

Preferred Method:

Online

Secure online registration at www.ahia.org.

Other Methods

Fax: If you are paying for your registration with a credit card, fax the registration with payment information to (303) 422-8894.

Mail: Send your completed registration form with payment to:
AHIA

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Wheat Ridge, CO 80033

Contact the AHIA toll-free at 888-ASK-AHIA (275-2442) or (303) 327-7546 with questions.

Confirmations

Online registrants will receive confirmations/receipts via email. All other registrants will receive written confirmations/receipts of registration in the mail.

The Association of Healthcare Internal Auditors, Inc. (AHIA) collects credit card information to make it easier for you to register for seminars and events online, as well as paying for other services. AHIA does not use or share credit card information for any other purpose. We retain such information as is needed for standard accounting record keeping requirements. Every step is taken to protect the loss, misuse, and alteration of the information under our control. If you prefer, please use a check or money order to make any necessary payments. Thank you.

AHIA Tax ID# 36-3666960

Contact AHIA toll-free at 888-ASK-AHIA (275-2442) or (303) 327-7546 with questions.

The preferred and most secure method of registration is online at: <http://www.ahia.org/>
Please copy for your files. Please photocopy form for additional participants.

Full Name _____

Title _____ Company _____

Mailing Address _____

City _____ State _____ ZIP _____

Daytime Phone _____ Email Address _____

Emergency Contact Name and Phone _____

Vegetarian Meals Requested Special Assistance Required _____

Registration Fee	On or before September 24	After September 24
Individual	<input type="checkbox"/> \$649	<input type="checkbox"/> \$699
Groups of 3 or More*	<input type="checkbox"/> \$619	<input type="checkbox"/> \$669
Non-member	<input type="checkbox"/> \$749	<input type="checkbox"/> \$799
Non-member Groups of 3 or More*	<input type="checkbox"/> \$719	<input type="checkbox"/> \$769

*Groups of 3 or more should have each participant complete a registration form and send payment under one cover.

Payment

Registration forms with payment must be postmarked or faxed **on or before September 24, 2007** to receive the lower fee.

Payment Method

Check payable to Association of Healthcare Internal Auditors American Express Discover MasterCard VISA

Account Number _____ Expiration Date _____

Security Code (last three digits on back of card) _____ Name as Printed on Card _____

Signature _____



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