May 28–29, 2009
Rome, Italy
Melia Roma Aurelia Antica Hotel

CONGRESS CO CHAIRS
Sue Egan, Vice President Compliance, AstraZeneca PLC, London, UK
Lori Queisser, Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation, Kenilworth, NJ, USA
Roeland van Aelst, Executive Director International WW Office Health Care Compliance & Privacy (EMEA, Canada, Lat-Am, Asia-Pac), Johnson & Johnson, Brussels, Belgium

FEATURED FACULTY
Guitelle Baghdadi-Sabeti, MD, Technical Officer, Medicines, Policies and Standards Department, World Health Organization, Geneva, Switzerland
Alicia D. Greenidge (Invited), Director General. International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Geneva, Switzerland
Wolf-Dietrich Guhl, Esq., Chief Compliance Officer, Healthcare Sector, Siemens AG, Munich, Germany
Marie-Claire Pickaert, Deputy Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium
Brenton L. Saunders, JD, MBA, Senior Vice President and President, Consumer Health Care, and Former Senior Vice President, Global Compliance, and Business Practices, Schering-Plough Corporation, Past President, Health Care Compliance Association, Founder, International Association of Privacy Professionals, Kenilworth, NJ USA
Heather Simmonds, Director, Prescription Medicines Code of Practice Authority, London, UK
John Wilkinson, Director General, Eucomed, Former Director General, Association of British Healthcare Industries Ltd., Brussels, Belgium
Jose Zamarriego, Director, Code of Practice Surveillance Unit, Farmaindustria, Madrid, Spain

PRECONFERENCE SESSIONS
• International Compliance Program Basics
• FCPA, Antibribery and Anticorruption
• Compliance Risk Management

SPECIAL SESSIONS ON
• Compliance in a Tough Economy
• The New EU Regulatory Pharmaceutical Package
• The WHO Approach to Fighting Anticorruption
• Increasing Regulatory Scrutiny
• Consolidation and Harmonization of Codes
• Managing Cultural Differences in a Consolidation and Harmonization Environment
• Fighting Corruption
• Fighting Counterfeits and Diversion: EU Pharma Package, US and WHO Proposals
• Transparency
• The Issues and Pitfalls of Sponsoring International Events
• Information for Patients Under the New Pharma Package
• Addressing the Challenges of Industry’s Reputation in a Transparent and Sustainable Fashion
• Investigations
• Clinical Trials in Emerging Markets
• Lessons Learned from the Siemens’ Case
• Life after Compliance: Why Compliance is Critical to a Business Leader
• Compliance Coordination with the Device Sector
• International Compliance Professional Roundtable
• Practical Side of Getting the Basics Right
Overview

Fundamental changes in the regulations applied to the pharmaceutical industry, public opinion on standards of ethical behavior and the global economic situation make this a challenging time to be a compliance professional or legal counsel responsible for ensuring adherence to applicable laws, regulations and codes of practice within our industry.

The PCF International Pharma Congress brings together senior global compliance professionals and legal counsel from around the world to share experiences and best practices to clarify these changes and potential responses to them. In Europe, the new Pharma Package (which focuses on three key areas: anti-counterfeiting initiatives, pharmacovigilance and providing information for patients) was finally adopted in December 2008. In the USA, the newly revised PhRMA code and the new Obama administration are beginning to have a significant impact across the pharmaceutical industry. In Asia, governments are bringing in new legislation and/or enforcing existing legislation to dispel perceptions of corruption and/or conflicts of interest within the public sector.

Keynote speakers representing the IFPMA, European Commission and Patients will give their views on the changes affecting our industry and how pharmaceutical companies can make a real difference during these challenging times. Panel discussions will focus on transparency and international compliance. There will also be smaller track discussions on the new European Pharma Package, clinical trials in emerging markets and a selection of case study sessions.

If you want to find out how to manage compliance in these challenging times, the PCF International Pharma Congress will give you the information that you need.

Who Should Attend

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<th>Category</th>
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<tr>
<td>Pharmaceutical Manufacturers</td>
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<td>Clinical Research Organizations</td>
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<td>Management Companies</td>
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<td>Health Care Regulators and Policy Makers</td>
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<td>Compliance Officers</td>
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About the Sponsor

The Pharmaceutical Compliance Forum (PCF) is a coalition of senior compliance professionals and legal counsel from more than 50 of the largest research-based pharmaceutical manufacturers. The PCF was founded in early-1999 by compliance professionals from the pharmaceutical industry to promote effective corporate compliance programs. The members meet twice a year, for two days, focusing on open and informal sharing of compliance information, best practices, and current developments in the field, and sponsors a two-day international compliance congress in the Spring and a three-day US compliance congress each Fall.
PCF Special Planning Committee

Co chairs:
Sue Egan, Vice President Compliance, AstraZeneca
Lori Queisser, Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation
Roeland van Aelst, Executive Director International, WW Office Health Care Compliance & Privacy (EMEA, Canada, Latin America, Asia-Pacific), Johnson & Johnson

Committee:
Ted Acosta, Esq., Principal, Ernst & Young LLP, Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services
John T. Bentivoglio, Esq., Partner, Skadden Arps LLP
Kathleen Boozang, Esq., Associate Dean for Academic Affairs, Cofounder, Health Law & Policy Program, and Health Law, Science and Technology Graduate Programs, Seton Hall Law School
Ian Dodds-Smith, Esq., Partner, Arnold & Porter LLP
Dominique Laymand, Esq., Senior Director Compliance & Ethics EMEA (Europe, Middle East, Turkey, Russia and Africa), Bristol-Myers Squibb
Michael Fadus, Compliance Director, Central & Eastern Europe, Schering-Plough Corporation
Gerard Geneen, Compliance Officer, Pharma Europe, GlaxoSmithKline
Linda Horton, Esq., Partner, Hogan & Hartson LLP
Georgia Keresty, Senior Vice President Pharmaceutical Compliance and Global Regulatory Affairs, Johnson & Johnson
Jonathon L. Kellerman, Partner, Pharmaceutical and Life Sciences Practice, PricewaterhouseCoopers LLP
Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP
Dominique Laymand, Esq., Senior Director Compliance & Ethics EMEA (Europe, Middle East, Turkey, Russia and Africa), Bristol-Myers Squibb
Maurits J.F. Lugard, MA, JD, LLM, Partner, Sidley Austin LLP, Former Member of the European Commission’s Legal Service
Maxine Nogard, International Compliance Officer, Wyeth
Dave O’Shaunessy, Vice President and Compliance Officer, Emerging Markets & Asia Pacific, GlaxoSmithKline
Michael Shaw, Global Head, Ethics & Compliance, Novartis Oncology
Paul B. Woods, BPharm, MA, MRPharmS, Global Compliance Policy Director, AstraZeneca, Co chair, EFPIA Information to Patients Task Force

Agenda
Pre-Conference Symposia
Thursday, May 28, 2009

7:00 am Congress Registration
8:00 am PRECONFERENCE I: INTERNATIONAL COMPLIANCE PROGRAM BASICS
Sue Egan, Vice President Compliance, AstraZeneca PLC, London, UK
Dominique Laymand, Esq., Senior Director Compliance & Ethics EMEA (Europe, Middle East, Turkey, Russia and Africa), Bristol-Myers Squibb, Paris, France
9:45 am Preconference Adjournment

8:00 am PRECONFERENCE II: FCPA, ANTI-BRIBERY AND ANTI-CORRUPTION
Paul V. Gerlach, Esq., Partner, Sidley Austin LLP, Former Associate Director, Division of Enforcement, US Securities & Exchange Commission, Washington, DC
SanDee Priser, Partner, Fraud Investigation and Dispute Services, Ernst & Young LLP, Germany
Philipp Rau, Associate, Clifford Chance, Frankfurt, Germany
9:45 am Preconference Adjournment

8:00 am PRECONFERENCE III: COMPLIANCE RISK MANAGEMENT
Thomas E. Costa, Vice President, U.S. Pharmaceuticals Compliance & Ethics, Bristol-Myers Squibb, Princeton, NJ, USA
Jonathon L. Kellerman, Partner, Pharmaceutical and Life Sciences Practice, PricewaterhouseCoopers LLP, Philadelphia, PA USA
9:45 am Preconference Adjournment

Conference Agenda
International Pharma Congress: Day I
Thursday, May 28, 2009

10:00 am Welcome and Overview of Day I
Morning Plenary Session
Sue Egan, Vice President Compliance, AstraZeneca PLC, London, UK
(Co chair)

10:15 am Opening Keynote Address
Nicola Braggio, Marketing Company President, AstraZeneca Italy, Milan, Italy

10:45 am Major Trends and Challenges of the Pharmaceutical Industry, in the EU and the Emerging Markets
Richard Bergstrom, MScPharm, Managing Director, Swedish Association of the Pharmaceutical Industry, Chairman, IFPMA Code Compliance Network, Chairman, EFPIA Code Steering Committee, Stockholm, Sweden

Continuing Education Credits
For those attendees seeking continuing education credits, the Congress will issue certificates of attendance which may be submitted to certification bodies.
11:15 am  Reputation is Everything — Pharma Transparency and Sustainability Challenges
Ted Acosta, Esq., Principal, Ernst & Young LLP; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, New York, NY, USA and Paris, France
Heather Simmonds, Director, Prescription Medicines Code of Practice Authority, London, UK
Willy Vanbuggenhout, JD, MBA, Chief Compliance Officer, Johnson & Johnson, Brussels, Belgium
Dave O’Shaunessy, Vice President and Compliance Officer, Emerging Markets and Asia Pacific, GlaxoSmithKline, Brentford, Middlesex, UK (Moderator)

12:15 pm  Networking Luncheon

1:30 pm  International Pharma Congress Concurrent Sessions I

1.01 Track I: Regulatory—The Burden of Compliance following the European Commission’s Sector Study: Where Do We Go From Here?
Tim Frazer, Esq., Partner, Arnold & Porter (UK) LLP; Former Professor and Dean of Law, Newcastle University, London, UK

1.02 Track II: Interactive Case Studies in Navigating the Issues and Pitfalls of Sponsoring International Events, including Practical Considerations Relating to Local Country Approvals, Educational Grants, Involvement in Content, Sponsorship of Invitees, etc.
Sue Egan, Vice President Compliance, AstraZeneca PLC, London, UK
Michael Shaw, Global Head, Ethics & Compliance, Novartis Oncology, Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, Florman Park, NJ USA
Linda Horton, Esq., Partner, Hogan & Hartson LLP; Washington, DC, USA and Brussels, Belgium (Moderator)

1.03 Track III: Industry and Corporate Standards—Transparency, Including:
- Current State of disclosure laws—global implications
- Where are manufacturers today?
- Data and systems challenges
- Current infrastructure is not sufficient to sustain
- Regulations present opportunities
- What should you be doing now?
Richard Bergstrom, MScPharm, Managing Director, Swedish Association of the Pharmaceutical Industry, Chairman, IFPMA Code Compliance Network, Chairman, EFPIA Code Steering Committee, Stockholm, Sweden
Jennifer Colapietro, Director, Pharmaceutical and Life Sciences Advisory Services, PricewaterhouseCoopers LLC, Florman Park, NJ, USA

2:30 pm  Transition Break

2:45 pm  International Pharma Congress Concurrent Sessions II

2.01 Track I: Regulatory—The New EU Pharma Package: Impact of Proposed Rules on Information to Patients
Maurits J.F. Lugard, MA, JD, LLM, Partner, Sidley Austin LLP; Former Member of the European Commission’s Legal Service, Brussels, Belgium
Paul B. Woods, BPharm, MA, MRPharmS, Global Compliance Policy Director, AstraZeneca, Co chair, EFPIA Information to Patients Task Force, Macclesfield, Cheshire, UK
Elisabethann Wright, Esq., Partner, Hogan & Hartson, Former Senior Legal Officer and Hearing Officer, EFTA Surveillance Authority, Brussels, Belgium

2.02 Track II: Fighting Corruption
Ted Acosta, Esq., Principal, Ernst & Young LLP; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, New York, NY, USA and Paris, France
Roeland van Aelst, Executive Director International, WW Office Health Care Compliance & Privacy, (EMEA, Canada, Lat-Am, Asia-Pac), Johnson & Johnson, Brussels, Belgium

2.03 Track III: Industry and Corporate Standards—Consolidation, Harmonization and Practical Implementation of Codes
Richard Bergstrom, MScPharm, Managing Director, Swedish Association of the Pharmaceutical Industry, Chairman, IFPMA Code Compliance Network, Chairman, EFPIA Code Steering Committee, Stockholm, Sweden
Thomas E. Costa, Vice President, U.S. Pharmaceuticals Compliance & Ethics, Bristol-Myers Squibb, Princeton, NJ, USA
Dominique Laymand, Esq., Senior Director Compliance & Ethics EMEA, (Europe, Middle East, Turkey, Russia and Africa), Bristol-Myers Squibb, Paris, France
Marie-Claire Pickaert, Deputy Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium
Jose Zamarriego, Director, Code of Practice Surveillance Unit, Farmaindustria, Madrid, Spain
Linda Horton, Esq., Partner, Hogan & Hartson LLP; Washington, DC and Brussels, Belgium (Moderator)

3:45 pm  Transition Break

4:00 pm  International Pharma Congress Concurrent Sessions III

3.01 Track I: Regulatory—Fighting Counterfeits and Diversion: Approaches to Fighting Counterfeits in EU Pharma Package, US and WHO Proposals
Pierre E. Dupouyré, Regional Compliance Director, Corporate Compliance, International Investigations and Programs, Pfizer, Inc., Berlin, Germany
Brett Rowland, Associate, Sidley Austin LLP; London, UK

Contact Information
INTERNATIONAL CALL CENTER: ROME, ITALY
Hours: 9:00 - 17:00 (Rome time)
Phone: +39 335 5697178  Fax: +39 06 3701169
E-mail: callcenter@serviziinternazionali.it

UNITED STATES CALL CENTER: NEVADA, USA
Hours: 9:00 a.m. - 5:00 p.m. (Pacific)
Toll-free: (800) 684-4549 (Continental U.S., Alaska and Hawaii only)
Phone: (775) 537-2311  Fax: (760) 418-8084
E-mail: registration@hcconferences.com

EXHIBIT/SPONSORSHIP INFORMATION: PENNSYLVANIA, USA
Hours: 9:00 a.m. - 5:00 p.m. (Eastern)
Toll-free: (800) 564-3750 (Continental U.S., Alaska and Hawaii only)
Phone: (215) 952-0866  Fax: (215) 952-0664
E-mail: joni.lipson@lipsonllc.com
3.02 Track II: Transparency—Working with Patient Groups
Richard Bergstrom, MScPharm, Managing Director, Swedish
Association of the Pharmaceutical Industry, Chairman, IFPMA
Code Compliance Network, Chairman, EFPIA Code Steering
Committee, Stockholm, Sweden
Allison Weber Shuren, MSN, JD, Arnold & Porter LLP,
Washington, DC
Paul B. Woods, BPharm, MA, MRPharmS, Global Compliance
Policy Director, AstraZeneca, Co chair, EFPIA Information to
Patients Task Force, Macclesfield, Cheshire, UK

3.03 Track III: Industry and Corporate Standards—Managing
Cultural Differences in a Consolidation and Harmonization
Environment
Sameh Farag, Regional Compliance Director, MEA, Schering-Plough
Corporation, Dubai
Yueh-Ming Tham, Esq., Senior Regulatory Consultant, DLA Piper,
Former Regional Compliance Director, Legal Division, Corporate
Compliance, Pfizer Inc., Former Deputy Public Prosecutor,
Singapore
Michael Fadus, Regional Compliance Director, Central & Eastern
Europe, Schering-Plough Corporation, Lucerne, Switzerland
(Moderator)

5:00 pm Adjournment and Networking Reception

International Pharma Congress:
Day II
Friday, May 29, 2009

8:30 am Welcome and Overview of Day II
Roeland van Aelst, Executive Director International WW Office
Health Care Compliance & Privacy (EMEA, Canada, Lat-Am,
Asia-Pac), Johnson & Johnson, Brussels, Belgium (Co chair)

8:45 am Compliance Coordination with the Device Sector
John Wilkinson, Chief Executive, Eucomed, Former Director
General, Association of British Healthcare Industries Ltd., Brussels,
Belgium

9:15 am The WHO Approach to Support Anticorruption
Guillette Baghdadi-Sabiti, MD, Technical Officer, Medicines,
Policies and Standards Department, World Health Organization,
Geneva, Switzerland

9:45 am Lessons Learned from the Siemens’ Case
Wolf-Dietrich Guhl, Esq., Chief Compliance Officer, Healthcare
Sector, Siemens AG, Munich, Germany

10:15 am Break

10:45 am International Pharma Congress
Concurrent Sessions IV

4.01 Track I: Regulatory—Clinical Trials in Emerging Markets
Mark Barnes, Esq., Managing Director, Huron Consulting Group,
New York, NY, USA
Kathleen Boozang, Esq., Associate Dean for Academic Affairs;
Cofounder, Health Law & Policy Program and Health Law,
Science and Technology Graduate Programs, Seton Hall Law School,
Newark, NJ, USA (Moderator)

4.02 Track II: International Investigations
Gary F. Giampetruzzi, Esq., Chief of Government Investigations,
Former Deputy Compliance Officer, International Investigations
and Programs, Pfizer Inc., New York, NY, USA
Kathleen M. Hamann, Esq., Trial Attorney, Fraud Section, US Department of Justice, Washington, DC
Frederic Raymond Miller, Partner, PricewaterhouseCoopers LLP,
Washington, DC, USA
Colleen Conry, Esq., Partner, Ropes & Gray LLP, Washington, DC
(Moderator)

4.03 Track III: International Compliance Case Studies
Sue Egan, Vice President Compliance, AstraZeneca PLC,
London, UK (Co moderator)
Allison Weber Shuren, MSN, JD, Arnold & Porter LLP,
Washington, DC (Co moderator)

12:00 pm Networking Luncheon

1:30 pm International Compliance Professional Roundtable
Gabor Danieli, Senior Director, Europe Middle East & Africa,
World Wide Office of Healthcare Compliance & Privacy, Johnson &
Johnson, Isy-le-Moulineaux, France
Dominique Laymand, Esq., Senior Director Compliance &
Ethics EMEA (Europe, Middle East, Turkey, Russia and Africa),
Bristol-Myers Squibb, Paris, France
Steve Mohr, Esq. (Invited), Global Compliance Officer, AstraZeneca,
London, UK
Lori Queisser, Senior Vice President, Global Compliance and Business
Practices, Schering-Plough Corporation, Kenilworth, NJ, USA
John T. Bentivoglio, Esq., Partner, Skadden Arps LLP, Former
Special Counsel for Healthcare Fraud, and Chief Privacy Officer,
Department of Justice, Washington, DC, USA (Co moderator)
Jonathon L. Kellerman, Partner, Pharmaceutical and Life Sciences
Practice, PricewaterhouseCoopers LLP, Philadelphia, PA, USA
(Co moderator)

2:45 pm Closing Remarks
Lori Queisser, Senior Vice President, Global Compliance and Business
Practices, Schering-Plough Corporation, Kenilworth, NJ, USA (Co
chair)

3:00 pm Adjournment
Pharmaceutical Compliance Forum

The Pharmaceutical Compliance Forum (PCF) is a coalition of senior compliance professionals and legal counsel from more than 50 of the largest research-based pharmaceutical manufacturers. The PCF was founded in early-1999 by compliance professionals from the pharmaceutical industry to promote effective corporate compliance programs. The members meet twice a year, for two days, focusing on open and informal sharing of compliance information, best practices, and current developments in the field, and sponsors a three-day compliance congress each Fall.

Save the Date!

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Special group rates of €164 single occupancy and €189 double occupancy per night (breakfast and 10% VAT included) have been arranged. Please make reservations directly with the MELIA ROMA AURELIA ANTICA and mention “Pharma Congress” to receive the reduced rate. Reservations, subject to availability, will be accepted until Monday, May 11th, 2009. After this date, reservations will be accepted on a space-available basis at the prevailing rate.

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HOW TO REGISTER FOR THE CONGRESS: Fully complete the following (one form per registrant, photocopies acceptable). Payment must accompany each registration.

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E-MAIL: Scan your form and send it to registration@hcconferences.com
FAX: Fax your registration with credit card information to: +1 760 418 8084 (include credit card information with registration)
MAIL: Conference Office, 3291 West Wilson Rd., Pahrump, NV, USA 89048
You may pay by bank transfer. You will receive a pro forma invoice which will include bank transfer information.

Please note that payment can be made only in Euros and via credit card or bank transfer.

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ADDRESS __________________________
CITY _____________________________ STATE/PROVINCE ____________ COUNTRY ________
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REGISTRATION OPTIONS:
Preconference Registration: The International Pharma Congress offers three optional preconference sessions on the morning of Day I of the conference. Please review the conference agenda for information about these preconference sessions. Please indicate under the Summary whether you intend to attend one of these preconference sessions. The registration fee for the preconference session is €295, plus VAT.

Conference Registration: Please indicate below your intent to attend the Congress. Delegates who register and pay by April 24, 2009 may register at the early bird discounted rates below. Delegates who pay after the lapse of the April 24, 2009 date must pay the full registration rates below.

VAT: All registrations are subject to Italian VAT (20.0%).
Registrants with a VAT number from a EU country must provide VAT number: ____________________ (required)

SUMMARY:
☑ Preconference only: ____________________ € 295
☑ Preconference I: International Compliance Program Basics
☑ Preconference II: FCPA, Anti bribery and Anticorruption
☑ Preconference III: Compliance Risk Management

EARLY BIRD DISCOUNTED RATE (received by April 24, 2009**) per person: €1,450
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SELECT YOUR CONCURRENT SESSIONS:
THURSDAY, MAY 28
1:30 pm Concurrent Sessions I ☑ 1.01 ☑ 1.02 ☑ 1.03
2:45 pm Concurrent Sessions II ☑ 2.01 ☑ 2.02 ☑ 2.03
1:30 pm Concurrent Sessions III ☑ 3.01 ☑ 3.02 ☑ 3.03
FRIDAY, MAY 29
10:45 am Concurrent Sessions IV ☑ 4.01 ☑ 4.02 ☑ 4.03

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THE THIRD INTERNATIONAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS AND BEST PRACTICES FORUM

Getting to a High Integrity Future Sustainably

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