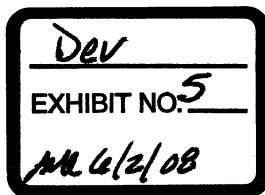



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2nd Annual Post-Approval Drug Safety Strategies Nov (13-14)

 Park Hyatt Philadelphia
 200 South Broad Street
 Philadelphia, PA 19102

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Schedule of Presentations:

November 13, 2007

- **07:30:00** Conference Registration and Morning Coffee (07:30-08:30)
- **08:30:00** Opening Workshop and Discussion; Case Study-Based Workshop: Identifying and Managing Pharmacovigilance Risk with a Business Partner (08:30-10:30)
 - Diana O'Connor
 - Joanna L. C. May
 - Edie Hudson
- **10:30:00** Morning Coffee Break (10:30-11:15)
- **11:15:00** Day I KEYNOTES: Structured Benefit-Risk Balance: Update on Industry Initiatives (11:15-12:00)
 - John Ferguson
- **12:00:00** Day I KEYNOTES: Integrating Drug Safety Knowledge Longitudinally Across a Compound's Lifecycle as well as Across the Organization's Entire Product Portfolio (12:00-12:45)
 - Judith M. Sills
- **12:45:00** Best Practice in Developing a Drug Safety Surveillance Program to Minimize Risk (12:45-13:15)
 - Alan Goldberg
- **13:15:00** Luncheon and Strategic Solutions Presentations or Lunch on Your Own (13:15-14:30)
- **14:30:00** CASE STUDY: Risk Management in Early Development: The Pre-Clinical/Clinical Safety Feedback Loop (14:30-15:15)
 CASE STUDY
 - Vivek Kadambi
 - John Ferguson
- **15:15:00** CASE STUDY: Successful EU Web-Based Post-Marketing Surveillance: the Actelion Experience (15:15-15:45)
 - Eleanor S. Segal
- **15:45:00** Networking Refreshment Break (15:45-16:15)
- **16:15:00** CASE STUDY: Interpreting the Guidelines on Risk Management Plans (16:15-16:45)
 - Robert G. Sharrar
- **16:45:00** SPECIAL CO-PRESENTATION: Benefits of Engaging the Research Enterprise - Methods, Signals, and Validation in a Healthcare System. (16:45-17:30)
 - Fran Cunningham
 - Alexander Ommaya
- **17:30:00** INTERACTIVE PANEL: Costs and Opportunities of Phase IV Risk Management Programs (17:30-18:15)
 - Gerald Faich
 - Jan Willem van der Velden
 - Daniel K. Burns
 - Patrick Caubel
- **18:15:00** Networking Reception
- **19:15:00** Close of Day One

November 14, 2007

- **07:45:00** Breakfast Workshop or Morning Coffee (07:45-08:15)
- **08:15:00** Chairperson's Opening Remarks (08:15-08:30)
- **08:30:00** Day II KEYNOTES: Proactive Risk Management - Philosophy, Strategy & Tactics (08:30-09:15)
 - J. David Haddox
- **09:15:00** Day II KEYNOTES: Decreasing Liability and Improving Brand by Employing a Proactive Communication and Risk-Management Strategy (09:15-09:45)
 - Vikram Dev
- **09:45:00** Day II KEYNOTES: CASE STUDY - Use of Genetic Biomarkers to Reduce Risk of Drug Associated Adverse Events (09:45-10:15) *Case Study*
 - Daniel K. Burns
- **10:15:00** Networking Coffee Break (10:15-10:45)
- **10:45:00** SPECIAL CO-PRESENTATION: The Other Side of the Benefit-Risk Ratio: Outcomes Research as a Means of Demonstrating Product Benefit (10:45-11:15)
 - Peggy Schrammel
 - Donald B. Chalfin
- **11:15:00** Practical Thinking Process in Selecting Safety Studies to Support Post-Marketing Safety Surveillance and Risk Assessment: Balance Feasibility, Cost, and Scientific Rigor (11:15-11:45)
 - Sean Zhao
- **11:45:00** INTERACTIVE PANEL: How Can Industry Make Drugs Safer? An Exploration of How To Improve Integration of Knowledge into Meaningful Actions (11:45-12:30)
 - John Ferguson
 - Sean Zhao
 - Uwe Maennl
 - J. David Haddox
 - Judith M. Sills
 - Alan Goldberg
- **12:30:00** Luncheon and Strategic Solutions Presentations (12:30-13:45)
- **13:45:00** Signal Prioritization: A Practical Problem in Pharmacovigilance (13:45-14:15)
 - Michael D. Blum
- **14:15:00** A Globally Usable Risk/Benefit Management Tool (14:15-14:45)
 - John Parkinson
- **14:45:00** Networking Refreshment Break (14:45-15:15)
- **15:15:00** Leveraging Drug Registry Tools to Assess Safety and Performance (15:15-15:45)
 - Annette Stemhagen
- **15:45:00** CASE STUDY: Drug Safety in Biologicals (15:45-16:15)
 - Nilima Justice
- **16:15:00** CASE STUDY: Risk Management Approaches: RevAssist@ and S.T.E.P.S. (16:15-16:45)
 - Carmen Castaneda
- **16:45:00** Chairperson's Closing Remarks (16:45-17:00)
- **17:00:00** Executive Forum Closes

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