

PDSS[09]

PACIFIC DRUG SAFETY SUMMIT



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www.pacificdrugssafetysummit.com

FRIDAY, SEPTEMBER 25, 2009

Mission Bay Conference Center at UCSF, 1675 Owens Street, San Francisco, CA

Conference Overview: Now in its third year, the annual **Pacific Drug Safety Summit** has grown to be one of the largest West Coast drug safety and pharmacovigilance conferences and networking events. Drug safety professionals and service providers alike keep coming back to PDSS each year due to the quality of the presentations, the diversity of the speakers and topics, and the opportunity to network with more than 100 drug safety practitioners and numerous vendors sponsoring the event.

This year's event offers an exciting agenda of presentations by internationally known thought-leaders in drug safety and pharmacovigilance. The program features eight contemporary topics, including quantitative safety signal detection and CIOMS VIII working group, risk benefit assessment, REMS/RMPs, registries, postmarketing safety studies and online spontaneous ADR report collection as well as use of electronic health record data in pharmacovigilance and unique challenges associated with data monitoring committees.

Attendees will have the opportunity to participate in networking breaks and interact with a diverse assemblage of drug safety and pharmacovigilance service providers and vendors. Breakfast and lunch will also be served.

BioSoteria, Inc., the conference organizer, is pleased to host this year's event at the new, state-of-the-art **Mission Bay Conference Center at UCSF**. Centered in UCSF's new 43-acre life sciences campus for teaching and research, the Conference Center is located just south of downtown in San Francisco.

We look forward to your joining us for PDSS[09].

A handwritten signature in black ink, appearing to read "Sally Van Doren".

Sally Van Doren, PharmD
President & CEO, BioSoteria



REGISTRATION: \$225*

* \$225 early bird attendee registration by August 31.
\$295 full registration after August 31.

Questions about registration? Email us today
pacificdrugssafetysummit@biosoteria.com
or call 1-866-660-5553 x013.





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PROGRAM AGENDA

7:45 am – 8:15 am	Registration & Continental Breakfast
8:15 am – 8:30 am	MORNING SESSION: NEW APPROACHES TO SAFETY DATA EVALUATION Hugh Tilson, MD, DrPH, <i>Moderator</i> Lauret Ballsun, RN, BSN, <i>Moderator</i>
8:30 am- 9:15 am	 Morning Keynote Presentation: Quantitative Safety Signal Detection: CIOMS Working Group VIII Andrew Bate, PhD, MA, <i>Director, Quantitative Epidemiologist, Pfizer Inc.</i>
9:15 am – 10:00 am	 Quantitative Risk Benefit Assessment Paul Coplan, Sc.D, MBA, <i>Senior Director, Risk Management, Global Safety Surveillance and Epidemiology, Wyeth Pharmaceuticals</i>
10:00 am – 10:30 am	Networking Break/Sponsor Exhibits
10:30 am – 11:15 am	 Religion and Politics: Controversial issues in Data Monitoring Committees David Kerr, MS, <i>Project Director, Axio Research</i>
11:15 am – 12:00 pm	 Use of Electronic Health Record Data in Pharmacovigilance Robert Dubois, MD, PhD, <i>Chief Medical Officer, Cerner Life Sciences</i>
12:00 pm – 1:00 pm	Lunch/Sponsor Exhibits

1:00 pm – 1:15 pm	AFTERNOON SESSION: CHANGING PHARMACOVIGILANCE PRACTICES Jim Buchanan, PharmD, <i>Moderator</i> Dana Lee, PharmD, <i>Moderator</i>
1:15 pm – 2:00 pm	 Afternoon Keynote Presentation: International Drug Safety Landscape: Challenge and an Opportunity for Change Rebecca Wang MD, FRCP, FACC, <i>Head, Regional Center, Asia Pacific Pharma Development, Drug Safety Operation, Roche</i>
2:00 pm – 2:45 pm	 Online Capture of AEs from Call Centers and Import into Safety Systems Brian Dinardo, <i>Partner, Foresight Group</i>
2:45 pm – 3:00 pm	Networking Break/Sponsor Exhibits
3:00 pm – 3:45 pm	 Risk Management Plan (RMP) for Extraneal Robin Geller, PhD, <i>Director of Risk Management, Global Pharmacovigilance, Baxter Healthcare Corporation</i>
3:45 pm – 4:30 pm	 Post-marketing Studies and Registries associated with REMS Cathy Sigler, DVM, PhD, <i>Sr. Director, Safety, Epidemiology, Registries, & Risk Management, United BioSource Corporation</i>
4:30 pm – 5:00 pm	Panel Discussion/Questions for the Audience
5:00 pm – 5:30 pm	Networking/Sponsor Exhibits
5:30 pm	Complimentary Shuttle to S.F. Airport

PROGRAM MODERATORS



Hugh Tilson, MD, DrPH, *Professor, Public Health Leadership, UNC School of Public Health, & Past Chair, CERTs National Steering Committee*



James Buchanan, PharmD
Sr. Vice President, Pharmacovigilance & Risk Management, BioSoteria, Inc.



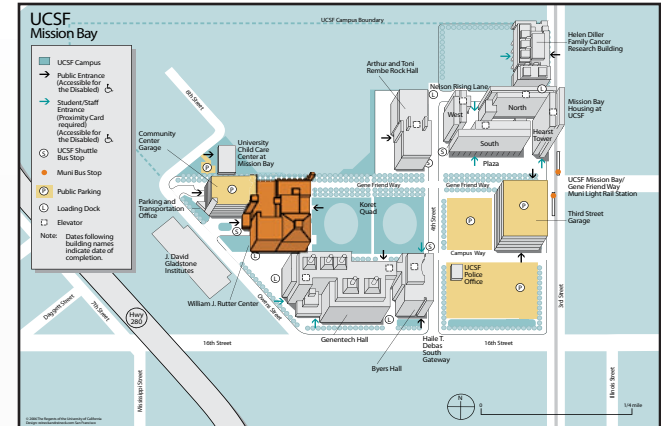
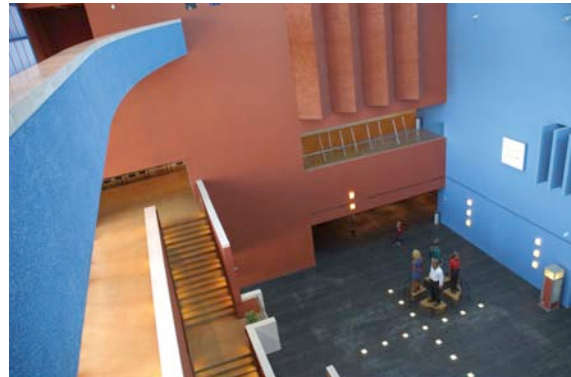
Dana Lee, PharmD
Sr. Director, Pharmacovigilance, Amylin Pharmaceuticals



Lauret Ballsun, RN, BSN
Drug Safety Consultant, LBC Pharmaceutical Professionals LLC

ABOUT THE CONFERENCE VENUE

The new Mission Bay Conference Center at UCSF offers technologically advanced meeting space to hold this internationally attended 3rd Annual Pacific Drug Safety Summit



Location: 1675 Owens Street, San Francisco, CA 94158. The Conference Center is conveniently located just south of downtown in San Francisco.

DRIVING DIRECTIONS

Parking Instructions

The Mission Bay Conference Center has covered parking available at a rate of \$24 per day maximum (subject to change). Cash or Credit Card payments are accepted for the parking fee at garage exit. No overnight parking is available. There is on-street parking available on a first come, first serve basis located along 16th Street and behind the conference center building. Public transportation is also available, as described on Mission Bay's website at <http://www.ahl-missionbay.com/directions.cfm>. If you have questions or require further information, please contact the conference center or email pacificdrugssafetysummit@biosoteria.com. Transportation details for attendees staying at Hotel Griffon will be provided by email.

Hotel Accommodations

Need a place to stay overnight? We have reserved a block of rooms at the nearby Hotel Griffon, an elegant boutique hotel located on San Francisco's Waterfront. Voted "Best Boutique Hotel" & "Best 24 Hour Getaway" by *San Francisco Magazine*, Hotel Griffon offers a pleasant and luxurious alternative to the chain hotels. Rooms will be held in a block until August 31, 2009. The special rate for Pacific Drug Safety Summit attendees is \$149/night, which includes continental breakfast and WiFi access. Reservations can be made for the Pacific Drug Safety Summit room block by calling the hotel directly at **1-415-495-2100** or [click here](#) to make a hotel reservation online.



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SPONSORS (click logos below to proceed to sponsor website)



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SPONSORSHIP AVAILABLE

Interested in sponsoring PDSS[09]? Space is available, but filling fast. Contact the conference host BioSoteria at contact@biosoteria.com or **1-866-660-5553 x010** today to reserve your sponsorship at the largest drug safety conference held in the Western US.

PDSS[09] is a GREEN event

The **PDSS[09]** organizers and sponsors have chosen to make this year's event as green as possible, starting with the selection of the Mission Bay Conference Center at UCSF which strives to create a healthy environment. The Center actively participates in recycling, composting, and utilizing biodegradable and organic foods and items, pens/paper made from recycled materials, compact fluorescent lights, and environmentally-responsible cleaning products. In addition, conference materials and handouts will be distributed digitally on a reusable memory stick rather than on paper. The selected hotel for overnight guests, the Hotel Griffon, also engages in best practices for energy efficiency and environmental sustainability, and is a certified member of the California Green Lodging Association.

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