

Association of Official Analytical Communities (AOAC)  
Southern California Section (SCS)



&

Western Compendial Discussion Group (WCDG)



U.S. PHARMACOPEIA

## Agenda

USP WCDG & AOAC SCS Joint Two-Day Regulatory & Compliance Conference,  
Chapman University, School of Pharmacy,  
Harry and Diane Rinker Health Science Campus,  
Terraced Auditorium Room No. 212  
9501 Jeronimo Rd, Irvine, CA 92618  
Critical Regulatory and Compliance Issues with the US FDA in the 21st Century

### DAY 1 - Monday, December 19, 2016

- 7:00 A.M. Registration & Continental Breakfast
- 8:15 A.M. Welcome Remarks by  
Sumit Sen, Ph.D., US FDA, PRL-SW, Irvine, CA, *President*, AOAC SCS  
& USP WCDG, & *Master of Ceremony*  
Ronald Jordan, Ph.D. *Dean*, Chapman University School of Pharmacy,  
Irvine, CA
- 8:30 A.M. **KEYNOTE SPEAKER:** Susan Rosencrance, Ph.D.  
Director, FDA/OMPT/CDER/OPQ/OLDP, Silver Spring, MD  
TOPIC: CDER's Current Thinking on Lifecycle Drug Products
- 9:20 A.M. Ramesh Raghavachari, Ph.D.  
Branch Chief, FDA/CDER/OPQ/OLDP/DPMI/PMBI,  
Silver Spring, MD  
TOPIC: Post-Marketing Regulatory Submissions: Common/Uncommon  
Deficiencies
- 10:10 A.M. Refreshment Break
- 10:30 A.M. Yan-Bo Yang, PhD.  
President, BioPharmadev, Corona, CA  
TOPIC: Importance of Analytical Characterization in Modernizing the  
Development and Production of Traditional Herbal Medicines
- 11:20 A.M. Heather Longden  
Senior Marketing Manager, Informatics and Regulatory Compliance,  
Waters Corporation, Milford, MA  
TOPIC: Ensuring Data Integrity in the Modern Analytical Laboratory
- 12:10 P.M. Sponsor Presentations
- 1:00 P.M. Lunch Break
- 2:15 P.M. Panel Discussion Session
- 4:30 P.M. Adjourn

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### **DAY 2 - Tuesday, December 20, 2016**

- 7:00 A.M. Registration & Continental Breakfast
- 8:30 A.M. **KEYNOTE SPEAKER:** Alonza Cruse, MS  
Pharmaceutical Quality Program Director, ORA—Office of Operations,  
Silver Spring, MD  
TOPIC: FDA's Assessment of Quality of Drug APIs and Drug Products
- 9:20 A.M. Desmond Hunt, Ph.D., M.S.,  
Senior Scientific Liaison, United States Pharmacopeia, Rockville, MD  
TOPIC: USP and Emerging Expectations for Extractables and Leachables  
for Container Closure Systems
- 10:10 A.M. Refreshment Break
- 10:40 A.M. Tao Wang, Ph.D.,  
Analytical Sciences, Allergan, Irvine, CA  
TOPIC: Assessment and Control of Potential Mutagenic Impurities per  
ICH Guideline (M7) with Case Studies
- 11:30 A.M. Frank Yang, Ph.D.,  
President/CEO, AcuTech Scientific Inc., San Diego, CA  
TOPIC: Quantitative Raman Spectroscopy
- 12:20 P.M. Sponsor Presentations
- 1:00 P.M. Lunch Break
- 2:15 P.M. Panel Discussion Session
- 4:30 P.M. Adjourn