Scientific Program

4th International Conference on
Pharmaceutical Regulatory Affairs

September 08-10, 2014   DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

“Organize your Events at OMICS Group Conferences”

Proposals are invited for organizing Symposia/Workshops at OMICS Group Conferences or OMICS Group will sponsor small events at your universities in related areas under the title of your own. These proposals can be sent to respective conference mail ids or to symposia@omicsonline.org

OMICS Group Conferences
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Email: regulatoryaffairs2014@omicsgroup.us
Day 1  September 08, 2014

Washington Room

09:30-09:55 Opening Ceremony

Keynote Forum

09:55-10:00  Introduction
Adam Sabouni, PharmaConsultz, USA

10:00-10:25  Title: Assessment of the antibacterial activity of actinomycetes isolated from terrestrial soil of King Saud University campus
Arunachalam Chinnathamibi, King Saud University, King Saud Arabia

10:25-10:50  Title: Extractables and leachables: Regulatory perceptive
Kishore Kumar Hotha, Novel Laboratories, USA

10:50-11:20  Title: Challenges & latest regulations have to know about medical devices in Middle East region
Sara Hegazi, Philips Healthcare, UAE

11:35-11:55  Title: Implementation of changes aligned to regulatory framework
Mohammad Iqbal Hossain, Novartis Limited, Bangladesh

11:55-12:15  Title: Pharmabiotics: A regulatory hurdle in Europe
Magali Cordaillat-Simmons, Pharmabiotic Research Institute, France

Track 1: Regulatory Affairs for Healthcare Products
Track 2: Regulatory Requirements for Pharmaceuticals
Track 3: Requirements for Medical Devices

Session Chair: Jerry Xu, WuXi AppTec, China
Session Co-Chair: Kishore Kumar Hotha, Novel Laboratories, USA

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13:15-14:10 Lunch Break @ Pre-function Area

14:10-14:30  Title: Combining nanotherapy and photomedicine: Design and synthesis of nanophotomedicine
Jayantha Jayaram, NIPER, India

14:30-14:50  Title: Have FDA expedited programs really shortened drug review time? an analysis of newly approved therapies and how FDA expedited programs have impacted drug development timelines
Krasimira Pekova, Artisan Healthcare Consulting, USA

14:50-15:10  Title: Key considerations of orphan products designation and registration regulation
Mona Mohammed, Medac GmbH, Germany

15:10-15:30  Title: Consent decree, why, how, and what to do?
Adam Sabouni, PharmaConsultz, USA

15:30-15:50  Title: Leadership role in implementing and maintaining pharmaceutical quality systems
Brian Hill, Brian Hill Consulting, USA

15:50-16:20  Title: Combination products and convergence: An overview of clinical benefits, regulatory issues & manufacturing challenges
Michael Drues, Vascular Sciences, USA

Coffee Break 16:20-16:35 @ Pre-function Area

17:00-18:00 Cocktails sponsored by Pharmaceutical Regulatory Affairs: Open Access @ Pre-function Area
Day 2                September 09, 2014

Washington Room

Keynote Forum

10:00-10:25       Jerry Xu
                  WuXi Apptec, China

Track 5: Biologics and Other Special Categories
Track 6: Best Industry Practices
Track 7: Business, Law Enforcement and Education

Session Chair: Adam Sabouni, PharmaConsultz, USA
Session Co-Chair: Arunachalam Chinnathambi, King Saud University, King Saud Arabia

Session Introduction

10:25-10:45       Title: Business and regulatory environment of biopharmaceuticals and biosimilars in Latin America
                  Ricardo Ibarra-Cabrera
                  INBIOXICA SA de CV/Asociacion Mexicana de Comites de etica en Investigacion, Mexico

10:45-11:05       Title: Herbal medicines: Product licence to traditional herbal registration in the UK
                  Mariam Aslam, ESCOP, UK

Coffee Break 11:05-11:20 @ Pre-function Area

11:20-11:40       Title: Implementing a periodic validation review program: A case study
                  Charles Stock, Integrated Project Services Inc., USA

11:40-12:10       Title: Biomedical nanotechnology: The smaller the thing, the bigger the challenge!
                  Michael Drues, Vascular Sciences, USA

12:10-12:30       Title: CAPA program management via the DMAIC methodology
                  Roger E Gould, Compliance Technology Group-South, USA

12:30-12:50       Title: Applied QbD hybrid approach: A case study
                  Charles Stock, Integrated Project Services Inc., USA

12:50-13:10       Title: Validation of a software as a service ERP System: Compliant use of cloud computing
                  David Hawley, IS Compliance and Validation, North America

13:10-13:30       Title: Investigating problems, applying risk management and creating sustainable solutions
                  Brian Hill, Brian Hill Consulting, USA

Lunch Break 13:30-14:30 @ Sessions Room

14:30-14:50       Title: Global regulatory best practices: Companion diagnostics
                  Abhishek Harde, Cognizant Technology Solutions Limited, USA

14:50-15:10       Title: Improving clinical research operations: Optimizing the use of current biomarkers
                  Augustine Onyeagha, Afriglobal Medicare, Nigeria

15:10-15:30       Title: Hidden danger of few extensively used vegetables and herbs renowned for the treatment of diabetes
                  Nasreen Fatima, University of Karachi, Pakistan

15:30-15:50       Title: A guide to an effective clinical trial protocol in cGMP & cGCP as a tool for sustenance of ethical
                  principles and regulatory requirements in the pharmaceutical and research
                  Peter Odeh, SNBL Clinical Pharmacology Center, USA

15:50-16:10       Title: Production and analysis of biosimilars and follow-on biologics in developing countries
                  Wael Ebied, SEDICO Pharmaceuticals, Egypt

16:10-16:30       Title: Production and analysis of biosimilars and follow-on biologics in developing countries
                  Rama Krishna Pidaparti, Wipro Technologies, USA

Poster Presentations

Coffee Break 16:30-16:45 @ Pre-function Area

17:00-18:00       Cocktails sponsored by Journal of Bioanalysis & Biomedicine @ Pre-function Area
Day 3  
September 10, 2014

Washington Room

Track 8: Intellectual Property Management
Track 9: Novel Strategies for Growth in the Pharma and Regulatory Environment

Session Chair: William Lee, Cato Research, USA

10:00-10:20  
Title: Risk based intercultural property assessment  
Jerry Xu, WuXi Apptec, China

10:20-10:40  
Title: USP monograph modernization-procedure review and development  
Donald Min, United States Pharmacopeial Convention, USA

10:40-11:00  
Title: Regulatory roadmap for initiating a cell therapy drug into clinical trials in the US  
William Lee, Cato Research, USA

11:00-11:20  
Title: A quality and regulatory it strategy for multi division life science companies  
Roger E Gould, Compliance Technology Group-South, USA

Coffee Break 11:20-11:35 @ Pre-function Area

11:35-11:55  
Title: A minimally invasive needle endoscope for the visualization of deep brain tissues in vivo  
Jun Ki Kim, Korea Basic Science and Technology, South Korea

11:55-12:15  
Title: Pharmaceutics & novel drug delivery systems  
Tariq Jamshaid, Surge Laboratories Pvt. Ltd., Pakistan

12:15-12:35  
Title: An investigation about complex formation tendencies of Fe (III) and Fe (II) with antiparkinsonian drug, levodopa at physiological pH  
Syed Zafar Abbas Zaidi, University of Karachi, Pakistan

12:35-12:55  
Title: Regulatory challenges of nano therapeutics  
Arpit Patel, Gujarat Forensic Sciences University, India

Lunch Break 12:55-13:55 @ Sessions Room

13:55-14:15  
Title: Saudi pharmaceutical market and pharmacy education  
Hussam Baghdady, Taibah University, King Saudi Arabia

14:15-14:35  
Title: Required amendments in the cosmetic products legislation in India  
Gupta R N, Birla Institute of Technology, India

14:35-14:55  
Title: Quality risk management system  
Rashid Mahmood, Surge Laboratories Pvt. Ltd., Pakistan

14:55-15:15  
Title: CHP-complaint handling process an approach in response to the dissatisfaction regarding substandard and a counterfeit drug  
Syed Zafar Abbas Zaidi, University of Karachi, Pakistan

15:15-15:30  
Award Ceremony

Coffee Break 15:30-15:45 @ Pre-function Area

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**Bookmark your dates**

**3rd International Summit on GMP, GCP & Quality Control**

September 25-26, 2014  Valencia Convention Centre, Spain

**5th International Conference on Pharmaceutical Regulatory Affairs**

August 03-05, 2015  Florida, USA