Scientific Program

4th International Conference on

Pharmaceutical Regulatory Affairs

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



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OMICS Group Conferences
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Day 1 September 08, 2014

08:00-09:00 Registrations

Washington Room

09:30-09:55 **Opening Ceremony**

Keynote Forum

09:55-10:00 **Introduction**

10:00-10:25 **Adam Sabouni**
PharmaConsultz, USA

10:25-10:50 **David Hawley**
IS Compliance and Validation, North America

10:50-11:20 **Michael Drues**
Vascular Sciences, USA

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

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

Session Introduction

11:35-11:55 **Title: Assessment of the antibacterial activity of actinomycetes isolated from terrestrial soil of King Saud University campus**
Arunachalam Chinnathambi, King Saud University, King Saudi Arabia

11:55-12:15 **Title: Extractables and leachables: Regulatory perceptive**
Kishore Kumar Hotha, Novel Laboratories, USA

12:15-12:35 **Title: Challenges & latest regulations have to know about medical devices in Middle East region**
Sara Hegazi, Philips Healthcare, UAE

12:35-12:55 **Title: Implementation of changes aligned to regulatory framework**
Mohammad Iqbal Hossain, Novartis Limited, Bangladesh

12:55-13:15 **Title: Pharmabiotics: A regulatory hurdle in Europe**
Magali Cordaillat-Simmons, Pharmabiotic Research Institute, France

Lunch Break 13:15-14:10 @ Sessions Room

14:10-14:30 **Title: Combining nanotheranostics and photomedicine: Design and synthesis of nanophotomedicine**
Jayeeta Bhaumik, 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: Leaderships 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 Saudi 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 Onyeaghala, 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 **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

Session Introduction

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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OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Summit on
GMP, GCP & Quality Control
September 25-26, 2014 Valencia Convention Centre, Spain

Bookmark your dates

OMICS Group Conferences
Accelerating Scientific Discovery

5th International Conference on
Pharmaceutical Regulatory Affairs
August 03-05, 2015 Florida, USA

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