205th OMICS Group Conference

Scientific Program

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs

September 08-10, 2014 Raleigh, 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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Day 1 September 08, 2014

08:00-09:00 Registrations

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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

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

11:30-11:50 **Title: Assessment of the antibacterial activity of actinomycetes isolated from terrestrial soil of King Saud University campus**
Arunachalam Chinnathambi, King Saud University, Kind Saudi Arabia

11:50-12:10 **Title: Extractables and leachables: Regulatory perceptive**
Kishore Kumar Hotha, Novel Laboratories, USA

12:10-12:30 **Title: Challenges & latest regulations have to know about medical devices in Middle East region**
Sara Hegazi, Philips Healthcare, UAE

12:30-12:50 **Title: Implementation of changes aligned to regulatory framework**
Mohammad Iqbal Hossain, Novartis Limited, Bangladesh

12:50-13:10 **Title: Pharmabiotics: A regulatory hurdle in Europe**
Magali Cordaillat-Simmons, Pharmabiotic Research Institute, France

Lunch Break 13:10-14:10

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, Pharma Consultz, USA

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

15:50-16:10 **Title: Combination products and convergence: An overview of clinical benefits, regulatory issues & manufacturing challenges**
Michael Drues, Vascular Sciences, USA

Coffee Break 16:15-16:30

17:00-18:00 Cocktails sponsored by **Pharmaceutical Regulatory Affairs: Open Access**

Day 2 September 09, 2014

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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, Pharma Consultz, USA
Session Co-Chair: Arunachalam Chinnathambi, King Saud University, KSA

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

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
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
17:00-18:00	Cocktails sponsored by **Journal of Bioanalysis & Biomedicine**

Day 3 September 10, 2014

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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
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 Private Limited, 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
13:55-14:15	**Title: Saudi pharmaceutical market and pharmacy education** **Hussam Baghdady,** Taibah University, KSA
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 Private Limited, 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

Bookmark your dates

OMICS Group Conferences
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5th International Conference on
Pharmaceutical Regulatory Affairs
August 03-05, 2015 Florida

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