



Scientific Program

International Conference & Exhibition on

Pharmaceutical Regulatory Affairs

6-7 September 2011, Baltimore, Maryland, USA



OMICS Group
Accelerating Scientific Discovery

Conference Secretariat

5716 Corsa Ave., Suite 110, Westlake,
Los Angeles, CA 91362-7354, USA
Tel: +1-650-268-9744, Fax: +1-650-618-1414
Toll free: 1-800-216-6499(USA & Canada)
E-mail: pharma2011@omicsonline.org

Scientific Program

18:00-19:00

Registrations

05 September 2011

Day 1 - 6 September 2011

07:00-08:30

Registrations

07:30-08:00

Breakfast

Breakout Room 1

08:30-08:55

Opening Ceremony

Keynote Forum

08:55-09:00

Introduction

09:00-09:25

Dr. Lodewyk Kock

University of the Free State, South Africa

09:25-09:50

Dr. Hu Yan

University of Yamanashi, Japan & University of Zhengzhou, China

09:50-10:15

Dr. Kyung Lee

National Cancer Institute, USA

Coffee Break 10:15-10:30

10:30-10:55

Dr. Patrick Leoni

Euromed Management, France

10:55-11:20

Dr. Eugenia Kharlampieva

University of Alabama at Birmingham, USA

Track 1.1: Regulatory Aspects of Biotechnological Products

Track 1.2: Quality Assurance/Quality Risk Management

Track 1.3: Clinical Trials in Emerging Markets

Track 1.4: Drug Regulatory Affairs

Session Introduction

11:25-11:45 **Title: Fingerprinting in low molecular weight heparins for regulating quality and equivalence**

Dr. Umesh R. Desai, Virginia Commonwealth University, USA

11:45-12:05 **Title: Cell therapy manufacturing tools and global regulatory environment**

Dr. Jiwen Zhang, GE Healthcare, USA

12:05-12:25 **Title: Successfully meeting the regulatory challenges of abuse/dependence liability evaluation in the development of new centrally-acting drugs**

Dr. David Heal, RenaSci, UK

Lunch Break 12:25-13:00

13:00-13:20 **Title: The importance of investigative site clinical research standard operating procedures (SOPs)**

Dr. Debbie Wilkerson, OV Clinical Trials, USA

13:20-13:40 **Title: Study design: How not to ruin a perfectly good product with a perfectly flawed study design**

Dr. Gizelle Baker, OV Clinical Trials, USA

13:40-14:00 **Title: Antibacterials: Past, Present – and Future?**

Dr. Nafsika H. Georgopapadakou, Independent Research Consultant, Canada

14:00-14:20 **Title: What is the place of knemometry in development of new inhaled corticosteroids**

Dr. Ole D. Wolthers, Aarhus University, Denmark

14:20-14:40 **Title: Occurrence of adverse drug reactions in the paediatric population**

Dr. Lise Aagaard, University of Copenhagen, Denmark

14:40-15:00 **Title: 'New' drugs and international regulatory mechanisms**

Dr. S. V. Eswaran, St. Stephen's College, India

15:00-15:20 **Title: Current guidelines and detected discrepancy in pharmacy practice care related to medication and patient safety in the population of the blind and deaf-blind**

Dr. Miroslav S. Sarac, Xavier University of Louisiana, USA

Coffee Break 15:20-15:30

- 15:30-15:50** Title: **New frontiers in clinical trials on drug-drug interactions**
Dr. Sanjita Das, Noida Institute of Engineering and Technology, India
- 15:50-16:10** Title: **Management of acute pharyngotonsillitis according to polish recommendations 2010**
Dr. Elzbieta Mazur, Medical University of Lublin, Poland
- 16:10-16:30** Title: **Single dose relative bioavailability and safety of a new quetiapine fumarate extended release formulation: Is there a food effect on XR performance**
Francisco E. Estevez-Carrizo, University of Montevideo Center of Biomedical Sciences, Uruguay
- 16:30-16:50** Title: **The infrastructure of Ghanaian medicine outlets and its suitability to support public health initiatives and services for malaria control**
Dr. Kwame Ohene Buabeng, Kwame Nkrumah University of Science & Technology, Ghana

Track 2.1: Clinical Trial Design for Medical Devices
Track 2.2: Biologics & Design Control
Track 2.3: Process Validation for Drugs and Biologics
Track 2.4: Bioengineered Pharmaceutical Products

Session Introduction

- 16:55-17:15** Title: **Vascular protective effects of selective PKC β inhibitor with Ruboxistaurin in Murine models**
Dr. Shi-Fang Yan, New York University School of Medicine, USA
- 17:15-17:35** Title: **Molecular mechanisms of bortezomib adverse effects and drug resistance**
Dr. Xinliang Mao, Soochow University, China
- 17:35-17:55** Title: **Cell therapy regulations – a critical factor in translational medicine**
Dr. Beate Wagner, University Hospitals of Munich, Germany
- 17:55-18:15** Title: **Pre-clinical and clinical development of an interferon beta 1a biosimilar for the treatment of multiple sclerosis**
Dr. Marcelo Kauffman, Bio Sidus SA, Argentina
- 18:15-18:35** Title: **The Turkish Oncology Group efforts to validate the applicability of various chemotherapeutic doses and schedules in Turkish cancer patients**
Dr. Nazim Serdar Turhal, Marmara University School of Medicine, Turkey
- 18:35-18:55** Title: **Anti-fibrotic actions of suramin: Novel uses of an old drug**
Dr. Shougang Zhuang, Brown University School of Medicine, USA

Breakout Room 2

Track 3.1: Drug Metabolism in Drug Discovery and Development
Track 3.2: Analytical Method Validations
Track 3.3: Epidemiology of Drug-Drug Interactions
Track 3.4: Biochemical Mechanisms of Drug Toxicity

Session Introduction

- 11:25-11:45** Title: **Drug synergism: The combined effects of Fluoxetine and Memantine on an animal model of obsessive compulsive disorder**
Dr. Raphael Wald, Tufts University School of Medicine, USA
- 11:45-12:05** Title: **The role of PK/PD and network analysis in the epidemiology of drug-drug interactions**
Dr. Ronald R. Burnette, University of Wisconsin School of Pharmacy, USA
- 12:05-12:25** Title: **Regulation of choroidal neovascularisation by tumstatin adenoviral gene delivery and its mechanism(s) action**
Dr. Sudhakar Akul Yakkanti, Boys Town National Research Hospital, USA

Lunch Break 12:25-13:00

- 13:00-13:20** Title: **The interaction between clopidogrel and proton pump inhibitors in Japanese patients**
Dr. Takeo Yasu, Shonan Kamakura General Hospital, Japan
- 13:20-13:40** Title: **Involvement of GABAA-ergic inhibition and NMDA-ergic excitation in finegrained temporal processing in audition: Relevance to “language specific learning impairment (LLI)**
Dr. Masashi Sakai, University of Yamanashi, Japan
- 13:40-14:00** Title: **Anti-PSMA antibodies and fragments for diagnosis and therapy of prostate cancer**
Dr. Ursula Elsasser-Beile, University Medical Center Freiburg, Germany

- 14:00-14:20 **Title: Preclinical evaluation of a PSMA \times CD3 Diabody for therapy of prostate cancer**
Dr. Patrick Buhler, University Medical Center Freiburg, Germany
- 14:20-14:40 **Title: Angiotensin type 1 receptors regulate a specific set of microRNA's in cardiovascular tissues including human arteries**
Dr. Soren Sheikh, University of Southern Denmark, Denmark
- 14:40-15:00 **Title: Comparison of different mobile phase modifiers according to their suitability for determination of chromatographic lipophilicity parameters**
Dr. Jolanta Flieger, Medical University of Lublin, Poland
- 15:00-15:20 **Title: Brazilian toxins targeting channels involved in pain, ischemia and cardiac arrhythmias**
Dr. Marcus Vinicius Gomez, Faculdade de Medicina UFMG, Brazil
- Coffee Break 15:20-15:30**
- 15:30-15:50 **Title: Application of nanostructured materials and polymer composite modified electrodes for electrochemical determination of drugs and biomolecules**
Dr. Shen Ming Chen, National Taipei University of Technology, Taiwan
- 15:50-16:10 **Title: Biosynthesis and diversification of lipoglycopeptide antibiotics**
Dr. Tsung-Lin Li, Academia Sinica, Taiwan
- 16:10-16:30 **Title: EU biosimilar regulations: An analysis of the data which has underpinned the approval of biosimilars granted marketing authorizations in Europe**
Dr. Gary Walsh, University of Limerick, Ireland
- 16:30-16:50 **Title: From basic research to drug development: The story of Copaxone (glatiramer acetate) in the treatment of multiple sclerosis and its new applications**
Dr. Rina Aharoni, The Weizmann Institute of Science, Israel
- 16:50-17:10 **Title: Carbon-nanotube-based field-effect transistors with biosensing functions**
Dr. Hu Yan, University of Yamanashi, Japan
- 17:10-17:30 **Title: Eltrombopag as first line treatment for acute radiation syndrome**
Dr. Yuhchayou Chen, James P. Wilmot Cancer Center, USA
- 17:30-17:50 **Title: Human artificial chromosome (HAC) vector with a conditional centromere for correction of genetic deficiencies in human cells**
Dr. Natalay Kouprina, National Institutes of Health, USA
- 17:50-18:10 **Title: New targets for treatment and diagnosis of schizophrenia spectrum disorders**
Dr. Tayfun Uzbay, Gulhane Medical School, Turkey
- 18:10-18:30 **Title: Polymeric prodrugs: Recent achievements and general strategies**
Dr. Neeraj Agrawal, Pacific College of Pharmacy, India
- 18:30-18:50 **Title: Signalling Pathways of Cardiac Hypertrophy**
Dr. Rohini, Pacific College of Pharmacy, India
- Cocktails Dinner** Sponsored by: *Journal of Bioequivalence & Bioavailability*
Sponsored by: *Journal of Bioanalysis & Biomedicine*

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2nd World Congress on

Pharmaceutical Regulatory Affairs

September 2012, Hyderabad, India