

55<sup>th</sup> OMICS Group Conference

# *Scientific Program*



International Conference and Exhibition on

## **Biowaivers & Biosimilars**

September 10-12, 2012 Hilton San Antonio Airport, USA



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### **OMICS Group Conferences**

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09:00-09:25

## Opening Ceremony

### Keynote Forum

09:25-09:30 Introduction

09:30-09:55 **Lisa J. Murray**

Absorption Systems, USA

09:55-10:20 **Paul A. Calvo**

Sterne, Kessler, Goldstein &amp; Fox P.L.L.C., USA

Coffee Break 10:20-10:35

10:35-11:00 **Michael D. McLean**

PlantForm Corporation, Canada

#### Track 1: Biosimilars: Innovator Pharmaceutical Products

#### Track 2: Biosimilars: Regulatory Approach

#### Session Introduction

11:00-11:20 **Title: The what million dollar question: Patent litigation and strategy under the Biologics Price Competition and Innovation act**

**Bryan J. Vogel**, Robins, Kaplan, Miller & Ciresi L.L.P., USA

11:20-11:40 **Title: The role of scientific justification in the nascent US biosimilars approval pathway**

**Ben Kaspar**, MMS Holdings Inc., USA

11:40-12:00 **Title: The role of patents in biosimilars and biobetters**

**Brian Dorn**, Barnes & Thornburg LLP, USA

12:00-12:20 **Title: Free to sell your biosimilar? The effect of the new FDA rules**

**D'vorah Graeser**, Graeser Associates International Inc., USA

#### Lunch Break 12:20-13:00

13:00-13:20 **Title: Understanding exclusivity periods in the Biologics Competition and Innovation Act of 2009 (BPCI Act)**

**Susan K. Finston**, Finston Consulting LLC, USA

13:20-13:40 **Title: What you can't see just might hurt (or maybe help) you and maybe someone else**

**C. Patrick McAtee**, SACHEM Inc., USA

13:40-14:00 **Title: Regulatory consideration of the assessment of biosimilar products**

**Jun Wang**, Duke University School of Medicine, USA

14:00-14:20 **Title: Some statistical issues on the evaluation of the similarity and interchangeability of biologics**

**Laszlo Endrenyi**, University of Toronto, Canada

14:20-14:40 **Title: Graphical representation of the assessment of inventive step for patents using the Problem-Solution-Approach (PSA)**

**Joachim Stellmach**, European Patent Office, Germany

14:40-15:00 **Title: Economic and regulatory scenario for biosimilars in Latin America**

**Valderilio Feijó Azevedo**, Edumed Biotech Federal University of Paraná, Brazil

#### Coffee Break 15:00-15:15

15:15-15:35 **Title: Biosimilars in emerging countries: Argentina**

**Gustavo Helguera**, University of Buenos Aires, Argentina

15:35-15:55 **Title: Developing biosimilars: Considerations, opportunities and challenges**

**Ming Wang**, Gan & Lee Pharmaceuticals, China

15:55-16:10 **Panel Discussion**

**Track 3: Skill Set for Biosimilars Development****Track 4: Clinical Studies for Biosimilars**

**16:10-16:30** **Title: Transgenic blood proteins: An abundant source for next generation therapies with worldwide availability**  
**William Velander**, University of Nebraska-Lincoln, USA

**16:30-16:50** **Title: Strategies for development and validation of immunogenicity assays to support preclinical and clinical biosimilar programs**

**Kelly S. Colletti**, Charles River Preclinical Services, USA

**16:50-17:10** **Title: The Danish HNPCC-system – Biomedical support to individual health care in hereditary colon cancer families**  
**Inge Thomsen Bernstein**, Hvidovre University Hospital, Denmark

**17:10-17:30** **Title: Use of human protein transgenic animal models for immunogenicity testing and their value for comparative studies of biosimilars**

**Melody Sauerborn**, TNO Triskelion BV, The Netherlands

**17:30-17:50** **Title: Application of nanotechnology in drug delivery**

**Rawia Khalil**, National Research Centre, Egypt

**17:50-18:10** **Title: Strategies and innovation in biosimilar drug development, achievement and challenges – An Indian perspective**  
**Viloo Morawala-Patell**, Avesthagen Limited, India

**18:10-18:25** **Panel Discussion**

**18:25-19:25** **Cocktails: Sponsored by Journal of Bioequivalence & Bioavailability**

**Day 2**

**September 11, 2012**

**Breakout 1**

**Track 5: Biosimilars Therapeutics****Track 6: Commercialization or Globalization of Biosimilars**

**Session Introduction**

**09:30-09:50** **Title: Biosimilars: Lessons learned from development to commercial launch**  
**Niranjan M. Kumar**, ABS Inc. USA

**09:50-10:10** **Title: PEG-Modified biosimilars: Potential role in the emerging global biosimilar market**  
**Pascal Bailon**, Bailon Consultants, USA

**10:10-10:30** **Title: The application of releasable pegylation linkers to improve the pharmaceutical properties of biosimilars and biobetters**

**Hong Zhao**, Enzon Pharmaceuticals Inc., USA

**10:30-10:50** **Title: High-Quality combinatorial approaches for protein discovery and development**

**Luke H. Bradley**, University of Kentucky College of Medicine, USA

**10:50-11:10** **Title: Biosimilar market overview, present and future**

**Leandro Mieravilla**, Biosimilar-Biotech Global Expert, Canada

**Coffee Break 11:10-11:25**

**11:25-11:45** **Title: Dietary salt, insulin resistance and salt-sensitive hypertension: A trio in Dahl salt-sensitive (S) rats**  
**Marlene Shehata**, Marlene Shehata Pharmaceuticals, Canada

**11:45-12:05** **Title: Biosimilars – From conformation, ligand binding and stability**  
**Rohanah Hussain**, Diamond Light Source, UK

**12:05-12:25** **Title: Developing of long acting glycoprotein hormones using gene fusion and gene transfer: From bench to clinics**  
**Fuad Fares**, University of Haifa, Israel

**12:25-12:45** **Title: Glucagon biosimilar: New perspective for low-price biopharmaceutical products for SUS**  
**Patricia Barbosa Pelegrini**, BioLife Brazil Ltd, Brazil

**Lunch Break 12:45-13:25**

**13:25-13:45** **Title: Expression of a complex biosimilar monoclonal antibody in alternate mammalian host system**  
**Hatim Motiwala**, Intas Biopharmaceuticals Ltd., India

**13:45-14:00** **Panel Discussion**

**Track 7: Plant Produced Biosimilar Products****Track 8: Aggregation and Immunogenicity of Biosimilars**

**Session Introduction**

**14:00-14:20** **Title: Mechanistic insights into protein aggregation and the development of rational approaches and predictive tools to stabilization of biopharmaceuticals**

**Veysel Kayser**, Massachusetts Institute of Technology, USA

**14:20-14:40** **Title: Plant expression platforms for human therapeutic proteins; A new era for biopharmaceuticals**

**Kathleen L. Hefferon**, University of Toronto, Canada

**14:40-15:00** **Plant-based production and preclinical analysis of biosimilar Trastuzumab**

**Michael D. McLean**, PlantForm Corporation, Canada

- 15:00-15:20** Title: Immunological aspects of formation of anti-drug antibodies against aggregated protein drugs  
Melody Sauerborn, TNO Triskelion BV, The Netherlands
- 15:20-15:40** Title: Identification of epitopes in Indian human papilloma virus 16 E6: A bioinformatics approach  
Ajay Kumar Singh, Amity University, India
- 15:40-15:55** Panel Discussion

Coffee Break 15:55-16:10

#### Breakout 2

##### Editorial Board Meeting

- 14:50-16:50** B2B Meeting
- 16:50-18:30** Poster Presentation
- 18:30-19:30** Cocktails: Sponsored by Journal Bioanalysis & Biomedicine

**Day 3 September 12, 2012**

#### Breakout 1

Track 9: BCS & IVIVC Based Biowaivers  
Track 10: Analytical Strategies

Session Introduction

- 09:30-09:50** Title: Approach for development of  $\omega$ -3 phospholipid dietary supplement to potential lipid drug  
Su Chen, Chainon Neurotrophin Biotechnology Inc., USA
- 09:50-10:10** Title: Bioanalytical challenges in development of biosimilars  
Carmine Lanni, Bioanalytical Development Services, USA
- 10:10-10:30** Title: Role of process controls in mitigating the risk associated with manufacturing of biosimilars  
Indu S. Javeri, CuriRx Inc., USA
- 10:30-10:50** Title: Current analytical techniques for analysis of carbohydrate containing biosimilars  
Parastoo Azadi, University of Georgia, USA
- 10:50-11:10** Title: A case study: Scientific challenges for the bioanalytical method development of biosimilars  
Rafiq Islam, Celerion Inc., USA
- 11:25-11:45** Title: Rapid characterization of formulations: Protein size, aggregate levels and viscosity  
David Goodall, Paraytec Limited, UK
- 11:45-12:05** Title: Effects of drying technology and polymers on integrity and biological activity of proteins  
Amal Ali Elkordy, University of Sunderland, UK
- 12:05-12:25** Title: From peptide hormone to ETEC toxin: Structure based design of a pharmaceutically relevant expression system  
Paul Rosch, University of Bayreuth, Germany
- 12:25-12:40** Panel Discussion

Coffee Break 11:10-11:25

Lunch Break 12:40-13:20

**Bookmark your dates**



2<sup>nd</sup> International Conference and Exhibition on

# Biowaivers & Biosimilars

September 23-25, 2013 Chicago, USA

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