Scientific Program

OMICS Group Conferences
Accelerating Scientific Discovery

International Conference and Exhibition on

Biowaivers & Biosimilars

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



"Organize your Events at OMICS Group Conferences"

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

OMICS Group Conferences
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18:00-19:00 Registrations September 09, 2012

Day 1 September 10, 2012

08:00-09:00 Registrations

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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 & 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** **Villoo 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 Jouranal 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 ω-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
	Coffee Break 11:10-11:25
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**
	Lunch Break 12:40-13:20

Bookmark your dates

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on

Biowaivers & Biosimilars

September 23-25, 2013 Chicago, USA

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