133rd OMICS Group Conference

Scientific Program

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on

Biowaivers & Biosimilars

September 23-25, 2013
DoubleTree by Hilton Hotel Raleigh-Durham Airport at RTP, NC, USA



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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*

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Email: *biosimilars2013@omicsonline.net*

Day 1 September 23, 2013

08:00-09:00 **Registrations**

Magnolia

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09:00-09:25 **Opening Ceremony**

Keynote Forum

09:25-09:30 **Introduction**

09:30-09:55 **Michael Retsky**
Harvard School of Public Health, USA

09:55-10:20 **Ivo Abraham**
University of Arizona, USA

10:20-10:45 **Russell Reeve**
Quintiles Inc, USA

Coffee Break 10:45-11:00 @ Oak

Felicitation to OCM's and EB Members

Group Photo

Track 1: Challenges and Regulatory Approach for Biosimilars

Session Chair: Jichao (Jay) Kang, Laureate Biopharmaceutical Services, USA

Session Co-Chair: Kevin W. McCabe, Sterne, Kessler, Goldstein & Fox, USA

Session Introduction

11:00-11:20 **Strategy for biosimilar development**
Jichao (Jay) Kang, Laureate Biopharmaceutical Services, USA

11:20-11:40 **The need for a reference product database for biosimilars**
Jeff Lyons, Absorption Systems, USA

11:40-12:00 **Freedom to operate issues and patent litigation considerations for biosimilars**
Sailesh Patel, Schiff Hardin LLP, USA

12:00-12:20 **Clearing the biosimilar patent thicket with IPRs**
Kevin W. McCabe, Sterne, Kessler, Goldstein & Fox, USA

12:20-12:40 **Integrated strategy for biosimilar development: A multidisciplinary approach for risk reduction**
Adriana E. Manzi, Atheln Inc, USA

Lunch Break 12:40-13:35 @ Oak

13:35-13:55 **Rituximab and biosimilars: Equivalence and reciprocity**
Zaina Qureshi, University of South Carolina, USA

13:55-14:15 **Compliance and thoughtfulness from idea to commercial production**
Deborah Thibodeaux, DKT Lab Consulting, USA

14:15-14:35 **Complexities of biosimilar product**
Alok Bandyopadhyay, Design Space Inpharmatics, USA

14:35-14:55 **Biosimilar in pharmerging markets**
Jun Wang, Duke University School of Medicine, USA

14:55-15:15 **Analytical characterization of biosimilar products to establish biosimilarity**
Fiona Greer, SGS M-Scan, UK

15:15-15:35 **Challenges in demonstrating biosimilarity and interchangeability of biosimilar products**
Rodeina Challand, PRA International, UK

Coffee Break 15:35-15:50 @ Oak

15:50-16:10 **Power without a patent: Twelve-year biologics data exclusivity period & a totality of the evidence standard for biosimilarity**
Jonathan Stroud, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, USA

16:10-16:30 **Patent issues for biologic and biosimilar products**
William Simmons, Sughrue Mion PLLC, USA

16:30-16:50 **The relevance of immunogenicity in preclinical development**
Ciriaco Maraschiello, Harlan Laboratories Inc., USA

16:50-17:10 **The data of the head-to-head use of two biosimilars of beta-interferon-1b in MS therapy at the Moscow MS Center**
Ekaterina Popova, Moscow Multiple Sclerosis Center, Russia

17:10-17:30 **Post-approval safe harbor…or not?**
Brian R. Dorn, Barnes & Thornburg LLP, USA

17:50-18:50 Cocktails Sponsored by **Journal of Bioanalysis & Biomedicine @ Oak**

Day 2 September 24, 2013

Magnolia

Keynote Forum

09:30-09:55 **Arturo Solis Herrera**
Human Photosynthesis Study Center, Mexico

09:55-10:20 **Leandro Mieravilla**
Cassara Biotech, Canada

Track 2: Emerging Biosimilars in Therapeutics

Session Chair: Russell Reeve, Quintiles Inc, USA
Session Co-Chair: Subhash Basu, University of Notre Dame, USA

Session Introduction

10:20-10:40 Development and manufacturing of a biobetter therapeutic: A case study
Michiel E. Ultee, Laureate Biopharmaceutical Services, Inc., USA

10:40-11:00 Development and manufacturing of a biobetter therapeutic: A case study
Kent Pryor, ZZ Biotech, USA

Coffee Break 11:00-11:15 @ Oak

11:15-11:35 Use of apoptosis assays as tools to compare biosimilarities of anticancer drugs or agents
Subhash Basu, University of Notre Dame, USA

11:35-11:55 Alpha ENaC-b as a gene therapy in salt-sensitive hypertension
Marlene Fouad Shehata, Marlene Shehata Pharmaceuticals, Canada

11:55-12:15 Reverting antibiotic tolerance of bacterial persisters by a brominated furanone, (Z)-4-bromo-5-(bromomethylene)-3-methylfuran-2(5H)-one
Jiachuan Pan, Syracuse University, USA

12:15-12:35 Comprehensive functional & biological characterization of biosimilar monoclonal antibodies
Daniel Galbraith, BioOutsource Ltd, UK

Lunch Break 12:35-13:30 @ Oak

13:30-13:50 Some possibilities in trial design to reduce sample size
Russell Reeve, Quintiles Inc., USA

13:50-14:10 Current analytical techniques for characterization of carbohydrate biosimilars
Parastoo Azadi, University of Georgia, USA

Track 3: Clinical Studies and Clinicians Prospects for Biosimilars
Track 4: Globalization of Biosimilars

Session Chair: Leandro Mieravilla, Cassara Biotech, Canada
Session Co-Chair: Jennifer Campbell, Merck Millipore, France

Session Introduction

14:10-14:30 Accelerating biosimilars mabs to market: A predefined process coupled with consultative services
Jennifer Campbell, Merck Millipore, France

14:30-14:50 Publication planning for biosimilars
Paul Lane, UBC- Envision Group, UK

14:50-15:10 Commercialization considerations for biosimilars
Steven Lehrer, Optimal Strategix Group, USA

15:10-15:30 Successful commercialization of biosimilars in Europe 1 market authorization, 27 markets
Marguarite Mensonides-Harsema, Medac GmbH, Germany

Coffee Break 15:30-15:45 @ Oak

15:45-16:05 Biosimilar market: Business development overview
Leandro Mieravilla, Cassara Biotech, Canada

16:05-16:25 Use of cardiac glycosides for inhibition of C-reactive protein and treatment of atherosclerosis -Road map to clinical applications
Oliver Zimmermann, Cardiovascular Center Oberallgau-Kempten, Germany

16:25-16:45 Biosimilars: Less than a decade and a new paradigm already?
Stephanie C. Finnegan, BioRASI, USA

16:45-17:05 Pharmacokinetics of venlafaxine and its major metabolite o- desmethylvenlafaxine in freely moving mice using automated dosing/sampling system
Bijay Aryal, Chitwan Medical College P.Ltd, India

14:40-15:30 Poster Presentations

17:00-18:00 Cocktails Sponsored by **Journal of Bioequivalence & Bioavailability** @ Oak

Day 3 September 25, 2013

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Track 6: Analytical Strategies

Session Chair: Michael Retsky, Harvard School of Public Health, USA
Session Co-Chair: Yunsheng Hsieh, Protech Pharmaservices Corporation, Taiwan

Session Introduction

09:30-09:50 Comparability study to support upstream and downstream process development
Rong-Rong Zhu, EMD Millipore, USA

09:50-10:10 How long should adjuvant chemotherapy be given?
Michael Retsky, Harvard School of Public Health, USA

10:10-10:30 Biosimilar characterization and comparability assessments experiences from a CRO GMP Protein chemistry laboratory
Leonard Bell, Covance Laboratories, UK

Coffee Break 10:30-10:45 @ Oak

10:45-11:05	**Robust, streamlined 2-D western blot workflow for evaluation of antibodies developed for detection of host cell proteins (HCP)** **Sricharan Bandhakavi,** Bio-Rad Laboratories, USA
11:05-11:25	**The use of high-speed liquid chromatography/Tandem mass spectrometry in the GLP assays for biosimilars** **Yunsheng Hsieh,** Protech Pharmaservices Corporation, Taiwan
11:25-11:45	**Silicon photonic bio-sensing, a new technology for immunogenicity testing** **Martin Gleeson,** Genalyte, USA
11:45-12:05	**The use of mass spectroscopy in the GMP analysis of biosimilars** **Mario DiPaola,** Blue Stream Laboratories Inc., USA

Track 5: Biosimilars Innovator Pharmaceutical Products
Track 7: Bioequivalence Assessment
Track 8: BCS & IVIVC Based Biowaivers

Session Chair: Ajay K. Banga, Mercer University, USA
Session Co-Chair: Hu Yan, Zhengzhou University, China

Session Introduction

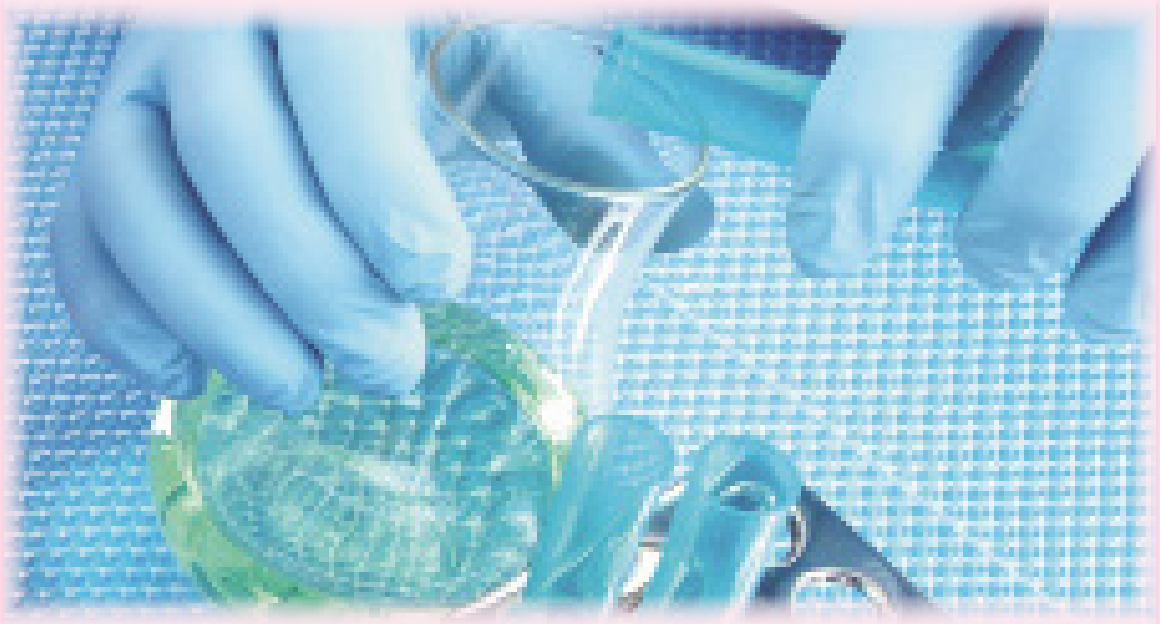
12:05-12:25	**Host cell protein characterization for bioprocess and product improvement** **Rong-Rong Zhu,** EMD Millipore, USA
12:25-12:45	**Novel pharmacologic and phenotypic methods to characterize carrier-mediated and nanoparticle agents as part of preclinical and clinical development** **William Zamboni,** University of North Carolina, USA

Lunch Break 12:45-13:30 @ Oak

13:30-13:50	**Applications of microchip-CE for high throughput screening of protein quality** **Bahram Fathollahi,** PerkinElmer, USA
13:50-14:10	**Human photosynthesis: a turning point in the understanding and treatment of Alzheimer's Disease** **Arturo Solis Herrera,** Human Photosynthesis Study Center, Mexico
14:10-14:30	**Human skin as an in vitro surrogate model for bioequivalence comparison of topicals** **Ajay K. Banga,** Mercer University, USA
14:30-14:50	**PNIPAM hydrogels and PLGA nanoparticles: Applications in drug delivery systems** **Hu Yan,** Zhengzhou University, China
14:50-15:10	**Antioxidative and anticholinesterase compounds from two closely related *Croton* species** **Ashwell Ndhlala,** University of KwaZulu-Natal, South Africa
15:10-15:30	**B-PAPM- Biological potency of certain antifeedant plant extracts against some pathogens for the management of human disease** **S. Abideen,** Dr. Zakir Hussain College, India

Award Ceremony

Coffee Break 15:30-15:45 @ Oak



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3rd International Conference and Exhibition on

Biowaivers & Biosimilars

October 27-29, 2014 Hyderabad, India

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