

**Tentative Scientific Program**

18:00-19:00  
Registrations

Sep-09-2012

**Day 1**  
Sep-10-2012

07:00-08:00 Registrations

08:00-08:30 Breakfast

**Breakout 1**

08:30-09:00

**Opening Ceremony**

**Keynote Forum**

09:00-09:05 Introduction

09:05-09:30 Lisa J. Murray, Absorption Systems, USA

09:30-09:55 Yet to be Confirmed

09:55-10:20 Yet to be Confirmed

10:20-10:45 Yet to be Confirmed

**Coffee Break 10:45-11:00**

**Track 1: Biosimilars: Innovator Pharmaceutical Products**

**Track 2: Biosimilars: Regulatory Approach**

**Session Introduction**

**Title: The role of scientific justification in the nascent us biosimilars approval pathway**

11:00-11:20 Ben Kaspar, MMS Holdings Inc., USA

**Title: The what million dollar question: Patent litigation and strategy under the biologics price Competition and Innovation act**

11:20-11:40

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

**Title: The role of patents in biosimilars and biobetters**

11:40-12:00

Brian Dorn, Barnes & Thornburg LLP, USA

**Title: New patent reform litigation options for biosimilars**

12:00-12:20

Paul A. Calvo, Sterne, Kessler, Goldstein & Fox P.L.L.C., USA

12:20-12:40

**Title: Regulatory consideration of the assessment of biosimilar products**

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

**Lunch Break 12:40-13:20**

**Title: What hath fda wrought: The February 2012 guidance and their implications for securing biosimilar approval**

**13:20-13:40 Michal Swit, Duane Morris LLP, USA**

**Title: The role of clinical trials in demonstrating similarity of biological medicinal products in the European Union**

**13:40-14:00 Cecil Nick, PARAXEL Consulting, UK**

**Title: Biosimilars panel: Opportunities and challenges to be overcome in the near term**

**14:00-14:20 Jennifer Brice, Frost & Sullivan, UK**

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

**14:20-14:40 Joachim Stellmach, European Patent Office, Germany**

**Title: IP strategies for the biosimilar arena**

**14:40-15:00 Ulrich Storz, Michalski Huettermann Patent Attorneys, Germany**

**Title: Biosimilars in emerging countries: Argentina**

**15:00-15:20 Gustavo Helguera, University of Buenos Aires, Argentina**

**Title: Developing biosimilars: Considerations, opportunities and challenges**

**15:20-15:40 Ming Wang, Gan & Lee Pharmaceuticals, China**

**Panel Discussion 15:40-15:55**

**Coffee Break 15:55-16:10**

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

**Session Introduction**

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

**16:10-16:30 Kelly S. Colletti, Charles River Preclinical Services, USA**

**Title: Transgenic blood proteins: An abundant source for next generation therapies with worldwide availability**

**16:30-16:50 William Velander, University of Nebraska, USA**

**Title: The Danish HNPCC-system – Biomedical support to individual health care in hereditary colon cancer families**

**16:50-17:10 Inge Thomsen Bernstein, Hvidovre University Hospital, Denmark**

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

**17:10-17:30 Melody Sauerborn, TNO Triskelion BV, The Netherlands**

**Title: Application of nanotechnology in drug delivery**

**17:30-17:50 Rawia Khalil, National Research Centre, Egypt**

**Panel Discussion 17:50-18:05**

**18:05-19:05 Cocktails: Sponsored by Journal of Bioequivalence & Bioavailability**

**Day 2**

**Sep-11-2012**

**Breakout 1**

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

**Session Introduction**

**Title: Development of antibody arrays for measuring biosimilar conformational comparability at molecular level**

**09:30-09:50 Xing Wang, Array Bridge Inc., USA**

**Title: Biosimilar market overview, present and future**

**09:50-10:20 Leandro Miravilla, Biosimilar-Biotech Global Expert, Canada**

**Title: Modified biosimilars: Potential role in the emerging global biosimilar market**

**10:20-10:40 Pascal Bailon, Bailon Consultants, USA**

**Coffee Break 10:40-10:55**

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

**10:55-11:15 Hong Zhao, Enzon Pharmaceuticals, USA**

**Title: The clinical development of monoclonal biosimilars**

**11:15-11:35 Cecil Nick, PARAXEL Consulting, UK**

**Title: Ghrelin antagonist: Advantages and side-effects**

**11:35-11:55 Maria Vlasova, University of Eastern Finland, Finland**

**Title: Biosimilar market growth trends in emerging markets**

**11:55-12:15 Syamala Ariyanchira, Independent Consultant, Malaysia**

**Title: Developing of long acting glycoprotein hormones using gene fusion and gene transfer: From bench to clinics**

12:15-12:35 Fuad Fares, University of Haifa, Israel

Lunch Break 12:35-13:15

**Title: Th1 immune response induced by Ipr1-PPE68 DNA vaccine in BALB/C mice model**

13:15-13:35 Yang Chun, Chongqing Medical University, China

**Title: Anticancer noscapinoids: Synthesis to nanomedicine**

13:35-13:55 Ramesh Chandra, University of Delhi, India

Panel Discussion 13:55-14:10

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

Session Introduction

**Title: Biosimilars: Lessons learned from development to commercial launch**

14:10-14:30 Niranjan M. Kumar, ABS Inc. USA

**Title: Plant-based production and preclinical analysis of biosimilar Trastuzumab**

14:30-14:50 Michael D. McLean, PlantForm Corporation, Canada

Coffee Break 14:50-15:05

**Title: Immunological aspects of formation of anti-drug antibodies against aggregated protein drugs**

15:05-15:25 Melody Sauerborn, TNO Triskelion BV, The Netherlands

15:25-15:45 Speech Opportunity Available

15:45-16:05 Speech Opportunity Available

Panel Discussion 16:05-16:20

Breakout 2

Editorial Board Meeting

Poster Presentations

16:20-19:20

**Scientific Partnering**

**Cocktails: Sponsored by Pharmaceutica Analytica Acta**

**Day 3**

**Sep-12-2012**

**Breakout 1**

**Track 9: Biowaivers  
Track 10: BCS & IVIVC Based Biowaivers  
Track 11: Bioequivalence Assessment  
Track 12: Analytical Strategies**

**Session Introduction**

**Title: Role of process controls in mitigating the risk associated with manufacturing of biosimilars**

**09:30-09:50 Indu S. Javeri, CuriRx Inc., USA**

**Title: Current analytical techniques for analysis of carbohydrate containing biosimilars**

**09:50-10:20 Parastoo Azadi, University of Georgia, USA**

**Title: Improving outcomes: A decade of industry and regulatory experience with BCS based biowaivers**

**10:20-10:40 Lisa J. Murray, Absorption Systems, USA**

**Coffee Break 10:40-10:55**

**Title: Approach for development of w-3 phospholipid dietary supplement to potential lipid drug**

**10:55-11:15 Su Chen, Chainon Neurotrophin Biotechnology Inc., USA**

**Title: Bioanalytical challenges in development of biosimilars**

**11:15-11:35 Carmine Lanni, Bioanalytical Development Services, USA**

**Title: Some statistical issues on the evaluation of the similarity and interchangeability of biologics**

**11:35-11:55 Laszlo Endrenyi, University of Toronto, Canada**

**Title: Rapid characterization of formulations: Protein size, aggregate levels and viscosity**

**11:55-12:15 David Goodall, Paraytec Limited, UK**

**Title: Taylor dispersion analysis, a rapid, nanolitre method to monitor protein aggregation behavior**

**12:15-12:35 Wendy Louise Hulse, University of Bradford, UK**

**Lunch Break 12:35-13:15**

**Title: Effects of drying technology and polymers on integrity and biological activity of proteins**

**13:15-13:35 Amal Ali Elkordy, University of Sunderland, UK**

**Title: A global perspective on the challenges of GLP/GCLP-bioanalysis for biosimilars**

**13:35-13:55 Aparna Kasinath, Clinigene International Limited, India**

**13:55-14:15 Speech Opportunity Available**

**14:15-14:35 Speech Opportunity Available**

**14:35-14:55 Speech Opportunity Available**

**14:55-15:15 Speech Opportunity Available**

**Panel Discussion 15:15-15:30**

**Editorial Board Meeting**