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OMICS Group Conferences
5716 Corsa Ave., Suite 110, Westlake Los Angeles, CA 91362-7354, USA
Phone: +1-650-268-9744, Fax: +1-650-618-1414, Toll free: +1-800-216-6499
Email: biosimilars2014@omicsonline.us
Day 1
October 27, 2014

Revised Day-1 Program
Hall 5

Opening Ceremony
10:30-10:55

Keynote Forum
10:55-11:00  Introduction
11:00-11:25  Nigel Rulewski
Quintiles Inc., USA
11:25-11:50  Mohan Dewan
R.K. Dewan & Co., India

Coffee Break: 11:50-12:00 @ Hall 4

Group Photo
Track 1: Challenges and Regulatory Approach for Biosimilars
Session Chair: Rodeina Challand, PRA Health Sciences, UK
Session Co-Chair: Ranjan Chakrabarti, United States Pharmacopeia India Pvt. Ltd., India

12:00-12:25  Steven Lehrer
Cipla Ltd., USA
12:25-12:50  Heike Schon
LUMIS International GmbH, Germany

Lunch Break 13:30-14:00 @ Hall 4

Workshop
17:10-18:10  BCS: A scientific and regulatory tool in drug development process
Sunita Dahiya, Globus College of Pharmacy, India
Bioavailability enhancement techniques for BCS Class II and Class IV drugs
Jithan Venkata Aukunuru, Mother Teresa College of Pharmacy, India

Symposium
18:10-19:10  Biosimilars and their prospective future in the market
Murali Bukkapatnam, TiE, India

Session Introduction
12:50-13:10  A double blind, phase 1, randomized, parallel-group, single dose, 2 arm, biosimilar study, of a "New Biologic" and "Comparator", intravenously administered to healthy subjects
Krishna Menon, Cellceutix Corporation, USA
Biosimilar regulations in the ASEAN
Shivraj Dasari, SLS Cell Cure Technologies Pvt. Ltd., India

14:00-14:20  Challenges in demonstrating biosimilarity and interchangeability of biosimilar products
Rodeina Challand, PRA Health Sciences, UK
Comparison of US/EU biosimilar guidelines
Kamali Chance, Quintiles Inc., USA

14:40-15:00  Challenges and its resolutions in the conduct of biosimilars clinical development
Chirag Shah, Cliantha Research Ltd., India
Being-similar: From benchside to bedside
Manish Mahajan, Lupin Ltd., India

15:20-15:40  Quality attributes of biologic products and standard setting process – USP perspective
Ranjan Chakrabarti, United States Pharmacopeia India Pvt. Ltd., India
Emerging trends and biosimilars regulation in India
R Manavalan, Annamalai University, India

16:00-16:20  Emerging trends in biosimilars and biologics
Kaiser Jamil, Bhagwan Mahavir Medical Research Centre, India
Potential value of biosimilars- will biosimilars be cost effective compared to the branded equivalents?
Shabana Khan, Ecron Acunova, India

16:40-17:00  Can excluding pharmaceuticals from patenting will lead to cost effective and quality drugs/biosimilars?
Shilpa Bhilegaonkar, PES’s Rajaram & Tarabai Bandekar College of Pharmacy, India

Coffee Break 17:00-17:10 @ Hall 4
### Keynote Forum

**Day 2  October 28, 2014**

**09:00-09:25**  
**Krishna Menon**  
Cellceutix Corporation, USA

**09:25-09:50**  
**Rodeina Challand**  
PRA Health Sciences, UK

### Track 2: Emerging Biosimilars in Therapeutics

**Session Chair:** Steven Lehrer, Cipla Ltd., USA  
**Session Co-Chair:** Daniel Galbraith, BioOutsource Ltd., UK

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<tr>
<th>Time</th>
<th>Title</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>09:50-10:10</td>
<td>Biological and functional characterization of anti-TNFα biosimilar drugs</td>
<td>Daniel Galbraith, BioOutsource Ltd., UK</td>
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<tr>
<td>10:10-10:30</td>
<td>Evaluation of immunogenicity in biotherapeutics</td>
<td>Surendra J Chavan, Quantimmune Solutions Pvt. Ltd., India</td>
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**Coffee Break 10:30-10:45 @ Hall 4**

### Track 3: Clinical Studies and Clinicians Prospects for Biosimilars

**Session Chair:** Naveen Kulkarni, Polyclone Bioservices Pvt. Ltd., India  
**Session Co-Chair:** Charu Manaktala, Quintiles Inc., India

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>11:45-12:05</td>
<td>Successful conduct of clinical trials to prove biosimilarity by defining a best fit outsourcing strategy</td>
<td>Heike Schoen, LUMIS International GmbH, Germany</td>
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<td>12:05-12:35</td>
<td>Intas–Merck Millipore: Partnership in biosimilars development strategy for emerging markets</td>
<td>Jennifer Campbell, Merck Millipore, France &amp; Shalini Sharma, Intas Pharmaceuticals Ltd, India</td>
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<td>12:35-12:55</td>
<td>Enzyme engineering: An innovative way to manage the economics of biosimilars- Polyclone case study</td>
<td>Naveen Kulkarni, Polyclone Bioservices Pvt. Ltd., India</td>
</tr>
<tr>
<td>12:55-13:15</td>
<td>Roadmap of stability studies for biosimilar product development</td>
<td>Rashbehari Tunga, Stelis Biopharma, India</td>
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**Lunch Break 13:15-14:00 @ Hall 4**

### Track 6: Analytical Strategies

**Track 7: Bioequivalence Assessment**

**Track 8: BCS & IVIVC Based Biowaivers**

**Session Chair:** Samit Kumar Nandi, West Bengal University of Animal and Fishery Sciences, India  
**Session Co-Chair:** Aparna Kasinath, Clinigene International Ltd., India
15:20-15:40
Best practices for high concentration ultrafiltration applications
Subhasis Banerjee, Merck Millipore, India

15:40-16:00
Bioanalytical strategy for biosimilars: Recommended steps for establishment of comparability
Aparna Kasinath, Cignalene International Ltd., India

Coffee Break 16:00-16:15 @ Hall 4

16:15-16:35
Understanding osteomyelitis and its solution through cost effective biomaterial based strategies
Samit Kumar Nandi, West Bengal University of Animal and Fishery Sciences, India

16:35-16:55
Virus filtration for biosimilar manufacturing: from needs to solutions
Tathagata Ray, Merck Millipore, India

16:55-17:15
An alternate approach for sialic acid estimation in erythropoietin by HPAEC-PAD method
R Jayachandran, United States Pharmacopeia India Pvt. Ltd., India

17:15-17:35
Analytical biosimilarity: Strategies and challenges
Shalini Sharma, Intas Pharmaceuticals Ltd., India

17:35-17:55
Alternate approaches addressing variability in ADCC assay
Prabhavathy Munagala, United States Pharmacopeia India Pvt. Ltd., India

11:00-12:30
Poster Presentations @ Hall 4

Day 3                October 29, 2014

Track 9: Intellectual Property Rights

Session Chair: Dieter Tzschoppe, European Patent Office, Germany
Session Co-Chair: Mohan Dewan, R.K. Dewan & Co., India

09:00-09:20
Biosimilars in the United States—Update on FDA implementation and other current issues
James C Shehan, Hyman, Phelps & McNamara, USA

09:20-09:40
The positive role of intellectual property in the creation of cost effective and affordable biosimilars
Mohan Dewan, R.K. Dewan & Co., India

09:40-10:00
IP checklist for similar biologics
Mita Sheikh, Krishna & Saurastri Associates, India

10:00-10:20
Patent issues in biopharmaceutical industry
Vijay Kumar, BioBridge Healthcare Solutions Pvt. Ltd., India

10:20-10:40
The exclusions from patentability and especially the rationale for medical use patents
Dieter Tzschoppe, European Patent Office, Germany

Coffee Break 10:40-10:55 @ Hall 4

10:55-11:15
Patenting of biosimilars in India and related issues
Vijay Kumar Makyam, IP Markets, India

11:15-11:35
Compulsory licensing: A delicate balance between biosimilars and innovations
Poongothai A R, IP Markets, India

11:35-11:55
Challenges for biosimilar generics
Vivek Kashyap, Lex Orbis IP Practice, India

11:55-12:15
Preparing for U.S. market entry—strategy considerations in view of BPCIA and AIA
Renita S Rathinam, Sughrue Mion PLLC, USA

Track 4: Globalization of Biosimilars
Track 5: Biosimilars Innovator Pharmaceutical Products
Track 10: Pharmacovigilance and its Challenges
Track 11: Plant Produced Biosimilar Products
Session Chair: J Vijay Venkatraman, Oviya MedSafe, India
Session Co-Chair: Arumugam Muruganandam, Affigenix Biosolutions Pvt. Ltd., India

Session Introduction

12:15-12:35
Biosimilars: Globalization of biosimilars
Ravi R Ghanghas, Govt. Medical College, India

12:35-12:55
A next generation sequencing approach drives target personalized therapy of acute myeloid leukemia
Giovanni Martinelli, Bologna University School of Medicine, Italy

12:55-13:15
Host cell protein and other impurity clearance assays for biosimilar development
Arumugam Muruganandam, Affigenix Biosolutions Pvt. Ltd., India

Lunch Break: 13:15-14:00 @ Hall 4

14:00-14:20
Safety concerns related to global biosimilars drug development
Nigel Rulewski, Quintiles Inc., USA

14:20-14:40
Pharmacovigilance of biosimilars: Challenges & possible solutions
J Vijay Venkatraman, Oviya MedSafe, India

14:40-15:00
Role of pharma industries in the improvement of pharmacovigilance system
Kamlesh Patel, Abbott HealthCare Pvt. Ltd., India

15:00-15:20
Synergism of ‘nutraceutical’ and ‘pharmaceutical’ for safety
Ekta K Kalra, Ekta K Kalra Writing Company, India

15:20-15:40
The key roles & responsibilities of pharmacists in biosimilars development
N Srinivas, Malla Reddy Institute of Pharmaceutical Sciences, India

Panel Discussion: 15:40-15:45
Coffee Break: 15:45-16:00 @ Hall 4

Young Researcher Forum

16:00-16:10
Bimodal gastroretentive drug delivery systems of lamotrigine: Formulation and evaluation
Rajasekhar Reddy Poonuru, St. Peter’s Institute of Pharmaceutical Sciences, India

16:10-16:20
Dissolution testing of nicotinamide cocrystals of a model BCS Class-II drug
Kale Mohana Raghava Srivalli, IIT (BHU), India

16:20-16:30
Medication usage and nutritional status in hemodialysis
S Chan Mubeena, Sri Padmavathi Mahila ViswaVidyalyam, India

16:30-16:40
Combined approach of biosimilar trastuzumab monoclonal antibody with nanoparticles targeted to prostate tumor cells
Dubey Satendra Kumar, JSS University, India

16:40-16:50
Effect of lipid digestion media on the fate of drug in lipid based nanoemulsion
R Suresh Kumar, JSS University, India

16:50-17:00
Design and synthesis of some novel antibacterial agents targeting Gyraxe B and Par E
Janarthanan T, JSS University, India

Bookmark your dates

4th International Conference and Exhibition on Biosimilars and Biologics
October 26-28, 2015 Baltimore, USA