Scientific Program

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference and Exhibition on
Biowaivers, Biologics & Biosimilars

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India



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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*

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

08:30-10:30 Registrations

Revised Day-1 Program
Hall 5

10:30-10:55 **Opening Ceremony**

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

12:00-12:25 **Steven Lehrer**
Cipla Ltd., USA

12:25-12:50 **Heike Schon**
LUMIS International GmbH, Germany

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

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

13:10-13:30 **Biosimilar regulations in the ASEAN**
Shivraj Dasari, SLS Cell Cure Technologies Pvt. Ltd., India

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

14:00-14:20 **Challenges in demonstrating biosimilarity and interchangeability of biosimilar products**
Rodeina Challand, PRA Health Sciences, UK

14:20-14:40 **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

15:00-15:20 **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

15:40-16:00 **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

16:20-16:40 **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

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

Day 2 October 28, 2014

Keynote Forum

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

Session Introduction

09:50-10:10 **Biological and functional characterization of anti-TNFα biosimilar durgs**
Daniel Galbraith, BioOutsource Ltd., UK

10:10-10:30 **Evaluation of immunogenicity in biotherapeutics**
Surendra J Chavan, Quantimmune Solutions Pvt. Ltd., India

Coffee Break 10:30-10:45 @ Hall 4

10:45-11:05 **Commercial opportunities in biosimilars**
Steve Lehrer, Cipla Ltd., USA

11:05-11:25 **Plant derived cyclopolypeptides: Targets for drug discovery**
Rajiv Dahiya, Association of Pharmacy Professionals, India

11:25-11:45 **Risk assessment: A pragmatic approach to develop biosimilars**
Harish Shandilya, INTAS Biopharmaceuticals Ltd., India

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

Session Introduction

11:45-12:05 **Successful conduct of clinical trials to prove biosimilarity by defining a best fit outsourcing strategy**
Heike Schoen, LUMIS International GmbH, Germany

12:05-12:35 **Intas–Merck Millipore: Partnership in biosimilars development strategy for emerging markets**
Jennifer Campbell, Merck Millipore, France **& Shalini Sharma,** Intas Pharmaceuticals Ltd, India

12:35-12:55 **Enzyme engineering: An innovative way to manage the economics of biosimilars- Polyclone case study**
Naveen Kulkarni, Polyclone Bioservices Pvt. Ltd., India

12:55-13:15 **Roadmap of stability studies for biosimilar product development**
Rashbehari Tunga, Stelis Biopharma, India

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

14:00-14:20 **Future of next generation biosimilars**
Kamlesh Patel, Abbott HealthCare Pvt. Ltd., India

14:20-14:40 **Clinical development of biosimilars: Overcoming challenges**
Charu Manaktala, Quintiles Inc., India

14:40-15:00 **Challenges faced in the development of biosimilars**
Hima Bindu Gujjarlamudi, Rajiv Gandhi Institute of Medical Sciences (RIMS), India

15:00-15:20 **Clinical trials of biosimilars in developing nations: obstacles and opportunities**
N Srinivas, Malla Reddy Institute of Pharmaceutical Sciences, India

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

Session Introduction

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, Clinigene 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

Session Introduction

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 Viswavidyalayam, 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 Gyrase B and Par E**
Janarthanan T, JSS University, India

Bookmark your dates

OMICS Group Conferences
Accelerating Scientific Discovery

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

OMICS Group Inc.
2360 Corporate Circle, Suite 400
Henderson, NV 89074-7722, USA
Ph: +1-888-843-8169
Fax: +1-650-618-1417
contact@omicsgroup.com

OMICS Publishing Group
5716 Corsa Ave., Suite 110, Westlake
Los Angeles, CA 91362-7354, USA
Ph: +1-650-268-9744
Fax: +1-650-618-1414
contact.americas@omicsonline.org

OMICS Group
SEZ Unit, Building No. 20, 9th Floor
APIIC Layout, HITEC City
Hyderabad-500081, Telangana, INDIA
Ph: 040-40131823, 040-47482222
contact.asiapacific@omicsonline.org

Toll free
USA & Canada: +1-800-216-6499
Australia: +1-800-651-097
Europe: 0805-080048