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Scientific Program

4th International Conference and Exhibition on

Biologics and Biosimilars

October 26-28, 2015 Baltimore, USA



OMICS International Conferences:
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Scientific Program

Day 1 October 26, 2015

09:00-09:45 Registrations

Harbor Room

09:45-09:55 **Opening Ceremony**

Keynote Forum

09:55-10:00 **Introduction**

10:00-10:30 **Patrick Lucy**
Pfenex Inc., USA

10:30-11:00 **Kamali Chance**
Quintiles, USA

Networking & Refreshments 11:00-11:15 @ Foyer

11:15-11:45 **Christopher J Leintz**
Pfizer Inc., USA

11:45-12:15 **Mark A Emalfarb**
Dyadic International Inc., USA

Group Photo

Track 1: Challenges and Regulatory Approach for Biosimilars
Track 2: Emerging Biosimilars in Therapeutics
Track 4: Emerging Biologics in Therapeutics
Track 13: Current Challenges in Advancement of Biologics

Session Chair: Patrick Lucy, Pfenex Inc., USA
Session Co-Chair: Jill A Myers, Momenta Pharmaceuticals, USA

Session Introduction

12:20-12:40 **Exploring government pricing and reimbursement policy challenges associated with biosimilars**
William A Sarraille, Sidley Austin LLP, USA

12:40-13:00 **The economic viability of a U.S. biosimilars industry**
Alex Brill, Matrix Global Advisors, USA

Lunch Break 13:00-13:45 @ Eden's Landing Restaurant

13:45-14:05 **Challenges and approaches in demonstrating biosimilarity at the physicochemical and biological level**
Jill A Myers, Momenta Pharmaceuticals, USA

14:05-14:25 **Clearing the path for market entry before the USPTO**
Y Jenny Chen, Wolf Greenfield & Sacks, PC, USA

14:25-14:45 **Similar biologics in India – legal and regulatory perspective**
Milind Antani, Nishith Desai Associates, India

14:45-15:05 **US biosimilars taking flight: Discussion of the key events and cases shaping the US biosimilar landscape**
Timothy J Shea, Sterne Kessler Goldstein & Fox PLLC, USA

15:05-15:25 **Biosimilars market access and penetration in the Obama care era –considerations for providers, payers, prescribers and patients**
Gary C Cupit, Somnus Therapeutics, USA

Networking & Refreshments 15:25-15:40 @ Foyer

15:40-16:00 **U.S. biosimilars – The courts interpret BCPIA steps**
Denise M Kettelberger, Sunstein Kann Murphy & Timbers LLP, USA

16:00-16:20 **AVX-470, an Orally-Delivered GI-Targeted anti-TNF Biobetter**
Neil L Schauer, Avaxia Biologics, USA

16:20-16:40 **Challenges of the recombinant pharmaceutical biosimilar proteins expression and enhanced refolded recovery from E.coli**
Vivek Kumar Morya, Inha University, Republic of Korea

16:40-17:00 **Emerging biosimilar in therapeutics: Where we are and what is future?**
Dipti Gulati, PJI Biotech, USA

Panel Discussion 17:00-17:20
Networking and Cocktail sponsored by Covance 17:30-19:00

Day 2 October 27, 2015

Harbor Room

Keynote Forum

10:00-10:30 **Sarfaraz K Niazi**
Therapeutic Proteins International, USA

10:30-11:00 **Angela Furlanetto**
Dimock Stratton LLP, Canada

Networking & Refreshments 11:00-11:15 @ Foyer

Track 3: Clinical Studies and Clinicians Prospects for Biosimilars
Track 5: Globalization of Biosimilars
Track 12: Regulatory Affairs and Intellectual Property Rights
Track 14: Biosimilar Companies and Market Analysis

Session Chair: Ronald A Rader, Biotechnology Information Institute, USA
Session Co-Chair: Lisa V Mueller, Michael Best & Friedrich LLP, USA

Session Introduction

11:15-11:35 **Impact of the biosimilars pipeline and nomenclature on market development**
Ronald A Rader, Biotechnology Information Institute, USA

11:35-11:55 **Evolution of the global biosimilars market: Lessons learned**
Raymond A Huml, Quintiles Inc., USA

11:55-12:15 **Biosimilars: Is the risk worth the reward**
James Harris III, Healthcare Economics LLC, USA

12:15-12:35 **Biosimilar Companies and Market Development Worldwide**
Lisa V Mueller, Michael Best & Friedrich LLP, USA

12:35-12:55 **Patent eligibility challenges to biologics under America Invents Act (AIA) and Myriad**
Raj S Davé, Pillsbury Winthrop Shaw Pittman LLP, USA

Lunch Break 12:55-13:40 @ Eden's Landing Restaurant

13:40-14:00 **Cost- Effective clinical trial design to detect immunogenicity and efficacy differences between biosimilar and innovator product.**
Candida Fratazzi, BBCR Consulting, USA

14:00-14:20 **Janssen Biotech V. Celltrion: The balance between the BPCIA and litigation**
Kerisha A Bowen, Dentons US LLC, USA

14:20-14:40 **Issues in the clinical development of the first wave of biosimilars**
Nigel Rulewski, Quintiles, USA

14:40-15:00 **Supplementary protection certificates (SPCs) in Europe – What is the 'basic patent' and what is the 'product'?**
Tom Carver, Wragge Lawrence Graham & Co, UK

Networking & Refreshments15:00-15:15@Foyer

Track 6: Biosimilars Innovator Pharmaceutical Products
8: Bioequivalence Assessment

Session Chair: Roman T Drews, LFB, USA
Session Co-Chair: Min Zhang, Fujifilm Diosynth Biotechnologies, USA

Session Introduction

15:15-15:35 **CMC consideration for biosimilar drug development and manufacturing process**
Marcus Mreyen , Protagen Protein Services, Germany

15:35-15:55 **Overcome challenges to manufacture of biosimilars through media/feed screening and cell culture process optimization**
Min Zhang, Fujifilm Diosynth Biotechnologies, U.S.A

15:55-16:15 **Erbitux biosimilar**
Alan L Epstein, USC Keck School Of Medicine, USA

16:15-16:35 **Production of biosimilar MAbs in transgenic animals– Opportunities and challenges**
Roman T Drews, LFB, USA

Day 3 October 28, 2015

Harbor Room

Track 7: Biosimilars Analytical Stratagies
Track 9: BCS & IVIVC Based Biowaivers
Track 10: Plant Produced Biosimilar Products
Track 11: Pharmacovigilance and its Challenges

Session Chair: Mario DiPaola, Bluestream Lab., USA
Session Co-Chair: Mariana Babayeva, Touro College of Pharmacy, USA

Session Introduction

09:30-10:15 **Workshop on A review of the how state regulators are dealing with biosimlairs. a case study of the Maryland policy debate and legislation**
Gene M Ransom III, University of Maryland and University of Baltimore School of Law, USA

10:15-10:35	**Safety and biosimilarity of ior®EPOCIM compared to Eprex® based on toxicologic, pharmacodynamic and pharmacokinetic studies in the Sprague-Dawley rat** **Gordon T Bolger,** Nucro-Technics, Canada
	Networking & Refreshments 10:35-10:50 @ Foyer
10:50-11:10	**Prevention potency of soaps and disinfectants on Vancomycin resistant Enterococcus faecalis infection** **Adetunji Olawale,** Osun State Polytechnic, Nigeria
11:10-11:30	**Bioanalytical challenges of biosimilar development; making you wish you had a mirror to put in front of the innovator drug** **Afshin Safavi,** BioAgilytix, USA
11:30-11:50	**Protein binding drug-drug interaction** **Mariana Babayeva,** Touro College of Pharmacy, USA
11:50-12:10	**The characterisation of biosimilar mAbs using biologically relevant and sensitive ADCC methodologies** **Andy Upsall,** BioOutsorce, UK
12:10-12:30	**Development of a biosimilar CMC strategy for the identification of critical quality attributes** **Samantha Little,** Covance Laboratories, UK
12:30-12:50	**Characterization of Glatiramer acetate C-terminal heterogeneity** **Mario DiPaola,** Bluestream Lab., USA
	Lunch Break: 12:50-13:35 @ Eden's Landing Restaurant
	Closing & Award ceremony

Bookmark your dates

5th European Biosimilars Congress

June 27-29, 2016 Valencia, Spain

http://biosimilars-biologics.pharmaceuticalconferences.com/europe/

6th International Conference and Exhibition on

Biologics & Biosimilars

October 20-22, 2016 Houston, USA

http://biosimilars-biologics.pharmaceuticalconferences.com/