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Tentative Program

11th European Biosimilars Congress

April 26-27, 2018 | Rome, Italy

Theme: "The developmental strategies and uptake of biosimilars through a decade in Europe"



For Available Speaker Slots

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11th European Biosimilars Congress

April 26-27, 2018 | Rome, Italy

Day 1 April 26, 2018	
Olimpica 2	
08:00-08:30	Registrations
08:30-08:45	Opening Ceremony
	Keynote Forum
08:45-09:00	Introduction
Keynote-1	Title: The Glycosylation aspects of biosimilarity
	Andras Guttman, Sciex Separations, USA
Keynote-2	Title: Establishing "Finger-print like" biosimilarity - critical characterization steps for biosimilar assessment
	Fiona M Greer, SGS Life Sciences, Switzerland
Keynote-3	Title: Patients' voice in biosimilar development and commercialization
	Francois-Xavier Frapaise, Biosimilars Consultant Paris, France
	Group Photo: 10:45-10:50
	Networking and Refreshments Break: 10:50-11:05
Sessions: Current Challenges in Developing Biosimilars | Analytical Strategies for Biosimilars | Biosimilar Companies and Market Analysis | Regulatory Approach of Biosimilars | Intellectual Property Rights | Emerging Biosimilars in Therapeutics	
Chair:	TBA
Co-Chair	TBA
Talk-1	Title: Application of new quality products of Type III antifreeze proteins and antifreeze glycoprotein
	Sakae Tsuda, National Institute of Advanced Science and Technology, Japan
Talk-2	Title: Technical challenges in developing biosimilar antibodies
	Emile Van Corven, Polpharma Biologics, Netherlands
Talk-3	Title: Identification and quantification of individual Host Cell Proteins (HCP's) in biosimilars and comparison with originator using SWATH mass spectrometry
	Thomas Kofoed, Alphalyse A/S, Denmark
Talk-4	Title: Bioanalytical methods for biosimilars: An approach
	R. Helena Bustos-Cruz, Universidad de La Sabana, Colombia
Talk-5	Title: The Bio-Immune(G)ene medicine and the use miRNAs to regulate the cell
	M. Carme Parés Santilari, European Bio Immune(G)ene Medicine Association, France
	Lunch Break 13:10-14:00 @ hotel Restaurants
Chair:	TBA
Co-Chair:	TBA
Talk-6	Title: Biosimilars in the United States: A progress report and a peek in to the future
	Kurt R. Karst, Phelps & McNamara, P.C., USA
Talk-7	Title: Challenges with Non-Biological Complex Drug (NBCD) products and their follow–on copies: Complex drugs in a complex environment
	David Ebsworth, Vifor Pharma Ltd, Switzerland
Talk-8	Title: How to meet FDA requirements for demonstration of interchangeability
	Kamali Chance, BioSciencesCorp, USA

Talk-9	**Title: "IN THE NAME" of biosimilars: Trademarks issues**
	Roberto Valenti, DLA Piper Milan, Italy
Talk-10	**Title: Getting the NHS ready for the biosimilar boom: Shifting attitudes, acceptance and appetites**
	Theo Christie, National Institute for Health Research, UK
	Networking and Refreshments Break: 16:05-16:20 @Foyer
Talk-11	**Title: Automated permethylation for glycosylation analysis of biologics using MALDI-TOF-MS**
	Archana Shubhakar, Ludger Ltd, UK
Talk-12	**Title: An *in vitro* functional assessment of a biosimilar rituximab and its originator**
	Fatemeh Torkashvand, Biotechnology Research Center, Iran
Talk-13	**Title: Biosimilar uptake in the MENA region strategies and challenges**
	Yazan Shaban, Brand Manager Biosimilar-Hikma Pharmaceuticals, Jordan
Panel Discussions	
Day 2 April 27, 2018	
Olimpica 2	
	Keynote Forum
Keynote-4	**Title: Toolbox needed for structural characteization and comparability studies of glycan biosimilars**
	Parastoo Azadi, University of Georgia, USA
Keynote-5	**Title: Optimizing clinical trials as part of the totality of data to support the marketing approval of biosimilars**
	Cecil Nick, PAREX International, UK
Keynote-6	**Title: Biosimilars in Europe — is there a golden rule to pricing?**
	Dominic Seitz, Simon-Kucher & Partners, Germany
	Networking and Refreshments Break: 10:30-10:45 @ Foyer
Sessions: **Current Challenges in Developing Biosimilars | Analytical Strategies for Biosimilars | Biosimilar Companies and Market Analysis | Legal Issues and BPCI Act | Biologic Drugs | Biological Medicine | Biowaiver Biobetters | Biosimilar Market and Cost Analysis**	
Chair:	**TBA**
Co-Chair:	**TBA**
Talk-14	**Title: Similar effects of peptides and proteins from animal venoms and of human Ly-6 proteins on nicotinic receptors**
	Victor Tsetlin, Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry, Moscow
Talk-15	**Title: Using organ-specific progenitor cells extracts in regenerative medicine**
	Anand Baskaran Padma Priya, ReeLabs Pvt. Ltd., India
Talk-16	**Title: Analysis of the pharmacological intervention and cognitive development through technology in the treatment of autism**
	Eraldo Martins Guerra Filho, Center for the Study of Advanced Systems of Recife, Brazil
Talk-17	**Title: Influence of fetal placenta extract on growth of experimental solid tumors**
	Oleksandr Kukharchuk, ReeLabs Pvt. Ltd., India
Workshop	

Workshop	**Title: The end of clinical trials in biosimilars development?**
	Francois-Xavier Frapaise, Biosimilars Consultant Paris, France
	Lunch Break: 13:00-13:50 @ hotel Restaurants
Talk-18	**Title: Influence of fetal placenta extract on growth of experimental solid tumors**
	Oleksandr Kukharchuk, ReeLabs Pvt. Ltd., India
Talk-19	**Title: Applications and advantages of gold nanoparticles as X-ray contrast agent**
	Logean Q. Al-Karam, Al-Nahrain University, Iraq
Talk-20	**Title: Applications and advantages of gold nanoparticles as X-ray contrast agent**
	Mohammed H. Alwan, Al-Nahrain University, Iraq
Talk-21	**Title: Understanding the nocebo effect can help optimizing treatment outcomes with biosimilars**
	Mourad F Rezk, Global Head of Medical and Scientific Affairs, Switzerland
Talk-22	**Title: Multiple zoonotic parasites identified in dog faeces collected in lower dir district, pakistan: A potential threat to human healt**
	Wali Khan, University of Malakand, Pakistan
Talk-23	**Title: Identification of biosimilarity in early process development and clone screening**
	Thomas Zahel, Exputec GmbH, Austria
	Networking and Refreshments Break: 16:05-16:25 @Foyer
Talk-24	**Title: Taeniosis/Neurocysticercosis control**
	Zbigniew Pawlowski, professor Medical University, Poland
Talk-25	**Title: How to speed up biologics RD**
	Jianguo Yang, Abpro-China Division, USA
Video Presentation	
Video Presentation	**Title: TBA**
	Andrei Lamsters, Estonia
Poster Presentations	
EBC01	**Title: CHO expression platform technology for cell line development of biosimilars**
	Cornelia Lindner, Sartorius Stedim Cellca's, Germany
EBC02	**Title: Mechanism of Action (MOA)-reflecting bioassays for biosimilar drug development**
	Steven Edenson, Promega Corporation, USA
EBC03	**Title: Biologics in autoimmune disease**
	Sandra Šimić, Ewopharma, Croatia
EBC04	**Title: TBA**
	Arkadiusz Wyrzucki, University of Zurich, Switzerland
EBC05	**Title: Detection of diverse virulence factors in phages Methicillin Resistance *Staphylococcus Aureus* (MRSA) isolated from mastitic cows**
	Atheer Aldoori, University of Baghdad, Iraq
Panel Discussion	
Awards & Closing Ceremony	

Collaborations

BSTP

European Nanoscience and Nanotechnology Association

Swiss Biotech Association ACADEMY

OCM - Euro Biosimilars 2018



Robert Salcedo
USA



Kamali Chance
USA



Francois-Xavier Frapaise
France



Fiona M Greer
Switzerland



Nelly Adel
USA



Dipti Gulati
USA



Andras Guttman
Hungary



Christoph Volpers
Germany

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Conference Highlights:

- *Current Challenges in Developing Biosimilars*
- *Emerging Biosimilars in Therapeutics*
- *Analytical Strategies for Biosimilars*
- *Regulatory Approach of Biosimilars*
- *Legal Issues and BPCI Act*
- *Innovative Approach for Biosimilars*
- *Biosimilars Research Pipeline*
- *Consequences of Brexit on Biosimilars*
- *Intellectual Property Rights*
- *Globalization of Biosimilars*
- *Bioequivalence Assessment*
- *Clinical Development of Biosimilars*
- *BCS and IVIVC Based Biowaivers*
- *Biosimilar Market and Cost Analysis*
- *Challenges in Biosimilars Pharmacovigilance*
- *Biosimilar Companies and Market Analysis*
- *Entrepreneurs Investment Meet*

For detailed sessions, please visit: http://biosimilars-biologics.pharmaceuticalconferences.com/europe/

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April 26-27, 2018 Rome, Italy

Euro Biosimilars - Past Participated Organisations



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11th European Biosimilars Congress

April 26-27, 2018 Rome, Italy

Euro Biosimilars - Past Participated Organisations

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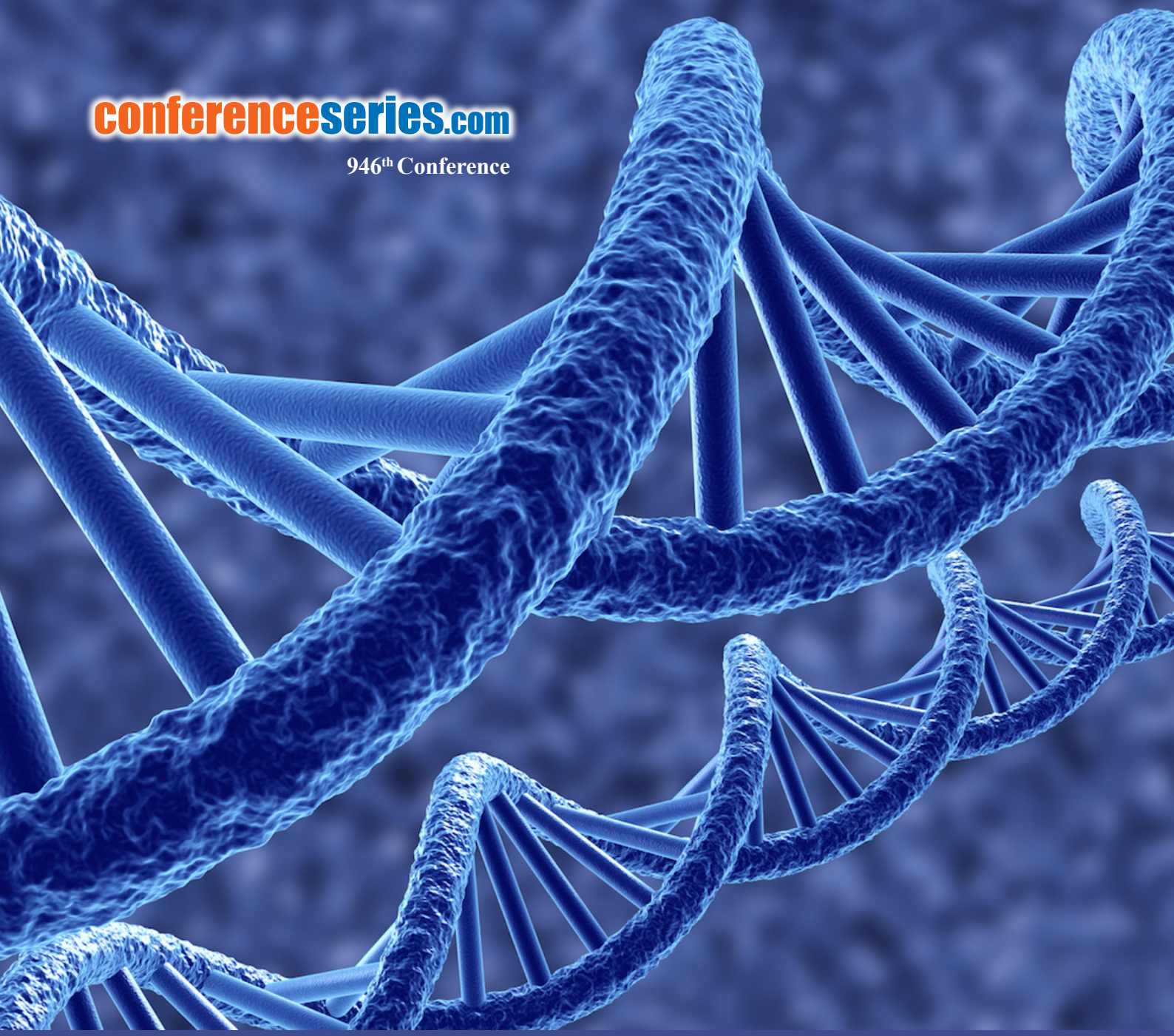
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Proceedings of

7th European Biosimilars Congress

May 15-16, 2017 Munich, Germany

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Day 1 May 15, 2017

Registrations

Lilli Palmer

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Opening Ceremony

Keynote Forum

Introduction

Title: The commercial landscape for biosimilars: Planning in an uncertain environment

Arthur G. Cook, ZS Associates, USA

Networking & Refreshment Break

Title: Intellectual property and regulatory interplay in biosimilars

Christoph Volpers, Michalski Hüttermann & Partner, Germany

Group Photo

Lunch Break

Sessions: Innovative Approach for Biosimilars | Clinical Development of Biosimilars | Emerging Biosimilars in Therapeutics

Session Chair: Tim Demuth

Session Introduction

Title: CMC considerations for biosimilar drug development

Ulrike Konrad, Karl Ruprecht Universität, Germany

Title: Search for unknown immunogenicity: An overview

Rosa Helena Bustos, University of La Sabana, Colombia

Networking & Refreshment Break

Title: Development of Etanercept biosimilar Erelzi™

Tim Demuth, Sandoz, Germany

Title: Development and *in-vivo* evaluation of Ofloxacin gastro-retentive drug delivery system

Dina E Abo Elezz, Pharos University, Egypt

Panel Discussion

Day 2 May 16, 2017

Lilli Palmer

Keynote Forum

Introduction

Title: How AbbVie tries to fend off world's blockbuster No 1 from generic competition

Ulrich Storz, Michalski Hüttermann & Partner, Germany

Networking & Refreshment Break

Title: Innovative, cost effective solution for self-administration of Bio-similar drugs

Tsachi Shaked, E3D Elcam Drug Delivery Devices, Israel

Menachem Zucker, E3D Elcam Drug Delivery Devices, Israel

Lunch Break

Sessions: Biosimilar Market and Cost Analysis | Analytical Strategies for Biosimilars | Globalization of Biosimilars

Session Chair: Tim Demuth

Session Introduction

Title: Evidence-based approach of CT-P13 to meet the expectations of different stakeholders

Stanley Seung Suh Hong, Celltrion Healthcare Co. Ltd., South Korea

Title: Multilevel characterization of biosimilars by CE-LIF and CE-MS

Andras Guttman, University of Pannonia, USA

Title: Development of a methodology for the evaluation of tumor necrosis factor antibody (anti-TNF-alpha) in patients with treatment of biological products through the use of Nanobiosensors

Efraín Esteban, University of La Sabana, Colombia

Title: Study of liver toxicity and its reversibility of Cassytha filiformis defatted ethanolic extract on mice

Armenia Nazar, University of Andalas, Indonesia

	Networking & Refreshment Break
	Poster Presentations
EBP 01	Title : Polymer-based prefillable syringes designed to minimize the aggregation risk of sensitive biodrugs
	Katsuyuki Takeuchi, Terumo Corporation, Japan
EBP 02	Title: Improved biologics workflow utilizing a single, automated platform to effectively monitor protein stability
	Marco Schwieder, NanoTemper Technologies GmbH, Germany
EBP 03	Title : Investigation of chemoprevention properties of Halopteris scoparia brown algae by using in vivo bioluminescent imaging"
	Özgenur Erdokur, Ege University, Turkey
EBP 04	Title : Inflectra-our experience on immunogenicity (case series)
	Rodica Olteanu, Colentina Clinical Hospital, Romania
EBP 05	"Title : Development of a methodology for the evaluation of tumor necrosis factor antibody (anti-TNFalpha) in patients with treatment of biological products through the use of nanobiosensors
	Zapata C, University of La Sabana, Colombia
EBP 06	Title : How can modeling and simulation optimize the clinical development of adalimumab biosimilar candidates?
	Bernardo Miguel-Lillo, SGS Exprimo, Belgium
	Award Ceremony



Day 1 October 19, 2016

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Opening Ceremony

Keynote Forum

Introduction

Title: Biosimilars: Latin America´s Coming On Board: Regulatory Approval and Market Access
Marlene Llópiz-Avilés, Association of Medical Specialists in the Pharmaceutical Industry, Mexico

Title: The Commercial Landscape for Biosimilars: Planning in an Uncertain Environment
Arthur G Cook, ZS Associates, USA

Title: Impact of Biosimilars on Patent Portfolio Development and Management
Kristin A. Connarn, McDermott Will & Emery, USA

Title: Biosimilars in treatment of multiple sclerosis in Iran
Hossein Pakdaman, Shahid Beheshti University of Medical Sciences, Iran

Title: Systematic Shortlisting of Candidate Molecules and Biosimilar/Biobetter Product Development: An Undergraduate Research Effort
Balram Pani, Bhaskaracharya College of Applied Sciences -University of Delhi, India

Title: Emerging biosimilars in the USA – quo vadis
Melissa Law, Technology Catalysts International, USA

Day 2 October 20, 2016

Keynote Forum

Title: Use of Biophysical Techniques for the Analysis of Biosimilars

Mario DiPaola, Blue Stream Laboratories, Inc, USA

Title: Scientific Factors in Biosimilar Product Development

Laszlo Endrenyi, University of Toronto, Canada

Title: Biosimilars Regulations: Updates from Canada

Oxana Iliach, Quintiles, Canada

Title: Brexit and Biosimilars
Dipti Gulati, PJI Biotech, USA

Title: Evolution of Structure-Function paradigm in Biopharmaceutics based on Global Regulatory Needs
Dinesh Palanivelu, Biocon Research Centre, Bangalore, India

Title: Using IPRs In the Biosimilars Context
Laura Burson, Sheppard, Mullin, Richter & Hampton LLP, USA

Title: nSMOL-Development of novel LCMS bioanalytical approach by Fab-selective quantitation of monoclonal antibodies using nano-surface and molecular orientation limited proteolysis
Takashi Shimada, SHIMADZU Corporation, Japan

Day 3 October 21, 2016

Networking Refreshments

5TH EUROPEAN BIOSIMILARS CONGRESS

Day 1 June 27, 2016

Keynote Forum

Title: Interchangeability of biological drug products
Laszlo Endrenyi, University of Toronto, Canada

Title: Evaluating immunogenicity biosimilars
Candida Fratazzi, BBCR Consulting, USA

Title: FDA/EMA Current thinking on totality of evidence for biosimilar approvals
Kamali Chance, Quintiles Inc., USA

Title: Supporting biosimilar clinical trials in the UK
Sarah Cooper, National Health Service , UK

Title: The emergence of orphan Biosimilars
Triona Bolger, Navigant Consulting, Inc, UK

Title: The importance of IP protection and SPCs for biologics and biosimilar products
Luder Behrens, Boehmert & Boehmert, Germany

Title: An update on the legal landscape for biosimilars in the USA
Paul A Calvo, Sterne, Kessler, Goldstein & Fox, USA

Title: Intellectual Property Issues in global biosimilar programs
Christoph Volpers, Michalski Hüttermann & Partner, Germany

Title: Dosing, double patenting and the US biosimilars landscape
Nabeela Rasheed, McAndrews, Held & Malloy, Ltd, USA

Day 2 June 28, 2016

Keynote Forum

Title: Startegies for biosimilars development
Andreu Soldevila, LeanBio Pro, Spain

Establishing "Finger-print like" biosimilarity-Critical characterization steps for biosimilar assessment.
Fiona M Greer, SGS Life Sciences, Switzerland

Title: Biosimilar development cost: Role of analytics
Dipti Gulati, PJI Biotech, USA

Title: Pharmacovigilance in cancer medicine
Luis H Camacho, Center for Oncology and Blood Disorders, Houston, USA

Title: Process Raman Spectroscopy for in-Line monitoring of mammalian cell cultures in real time
Alexander Pitters, Kaiser Optical Systems, SARL, France

Title: Analytical assessment of biosimilarity – Considerations in study design
Christina Vessely, Biologics Consulting, USA

Title: Overcoming the challenges of biosimilar development as a mid-size player
Ruediger Jankowsky, Cinfa Biotech, Germany

Title: Recommendations from the AAPS LBABFG Biosimilars Action Program Committee for the validation of pharmacokinetic and immunogenicity assays in support of Biosimilar drug development
Aparna Kasinath, Syngene International Limited, India

Title: Impact on technology integration on better and faster Biosimilars pipeline
Christelle Dagoneau, Catalent Biologics, USA

Title: Biosimilar Globalization- A silver lining in untested waters
Candida Fratazzi, BBCR Consulting, USA

Title: From neuronal networks to neuromodulation with biosimilars
Luis Ulloa, Rutgers-New Jersey Medical School, USA

Title: High throughput assays for the determination of the potency and comparability of Biosimilars and innovator products
Michael G Tovey, INSERM, France

Title: Growth potential of Biosimilar products in Bangladesh
Md. Abu Zafor Sadek, Renata Ltd., Bangladesh

Day 1 October 26, 2015

Keynote Forum

Patrick Lucy
Pfenex Inc., USA

Christopher J Leintz
Pfizer Inc., USA

Kamali Chance
Quintiles, USA

Mark A Emalfarb
Dyadic International Inc., USA

Exploring government pricing and reimbursement policy challenges associated with biosimilars
William A Sarraille, Sidley Austin LLP, USA
The economic viability of a U.S. biosimilars industry
Alex Brill, Matrix Global Advisors, USA
Challenges and approaches in demonstrating biosimilarity at the physicochemical and biological level
Jill A Myers, Momenta Pharmaceuticals, USA
Clearing the path for market entry before the USPTO
Y Jenny Chen, Wolf Greenfield & Sacks, PC, USA
Similar biologics in India – legal and regulatory perspective
Milind Antani, Nishith Desai Associates, India
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
Biosimilars market access and penetration in the Obama care era –considerations for providers, payers, prescribers and patients
Gary C Cupit, Somnus Therapeutics, USA
U.S. biosimilars – The courts interpret BCPIA steps
Denise M Kettelberger, Sunstein Kann Murphy & Timbers LLP, USA
AVX-470, an Orally-Delivered GI-Targeted anti-TNF Biobetter
Neil L Schauer, Avaxia Biologics, USA
Challenges of the recombinant pharmaceutical biosimilar proteins expression and enhanced refolded recovery from E.coli
Vivek Kumar Morya, Inha University, Republic of Korea
Emerging biosimilar in therapeutics: Where we are and what is future?
Dipti Gulati, PJI Biotech, USA

Day 2 October 27, 2015

Keynote Forum

Sarfaraz K Niazi
Therapeutic Proteins International, USA

Angela Furlanetto
Dimock Stratton LLP, Canada

Impact of the biosimilars pipeline and nomenclature on market development
Ronald A Rader, Biotechnology Information Institute, USA
Evolution of the global biosimilars market: Lessons learned
Raymond A Huml, Quintiles Inc., USA
Biosimilars: Is the risk worth the reward
James Harris III, Healthcare Economics LLC, USA
Biosimilar Companies and Market Development Worldwide
Lisa V Mueller, Michael Best & Friedrich LLP, USA
Patent eligibility challenges to biologics under America Invents Act (AIA) and Myriad
Raj S Davé, Pillsbury Winthrop Shaw Pittman LLP, USA
Cost- Effective clinical trial design to detect immunogenicity and efficacy differences between biosimilar and innovator product.
Candida Fratazzi, BBCR Consulting, USA
Janssen Biotech V. Celltrion: The balance between the BPCIA and litigation
Kerisha A Bowen, Dentons US LLC, USA
Issues in the clinical development of the first wave of biosimilars
Nigel Rulewski, Quintiles, USA
Supplementary protection certificates (SPCs) in Europe – What is the 'basic patent' and what is the 'product'?
Tom Carver, Wragge Lawrence Graham & Co, UK
CMC consideration for biosimilar drug development and manufacturing process
Marcus Mreyen , Protagen Protein Services, Germany
Overcome challenges to manufacture of biosimilars through media/feed screening and cell culture process optimization
Min Zhang, Fujifilm Diosynth Biotechnologies, U.S.A

Erbitux biosimilar
Alan L Epstein, USC Keck School Of Medicine, USA
Production of biosimilar MAbs in transgenic animals– Opportunities and challenges
Roman T Drews, LFB, USA

Poster Presentation

Identification and quantification of flavonoids and their glycosides for quality assessment of Terminalia species applying liquid chromatography hyphenated with mass spectrometric techniques
Awantika Singh, Central Drug Research Institute, India
Patients Satisfaction on Antiretroviral Therapy Monitoring Laboratory Services in public Hospitals, Addis Ababa, Ethiopia.
Tedla Mindaye, Addis Ababa University, Ethiopia
Improving injection force of high viscous drugs by a unique, commercially available needle created by using tapered technology
Mitsuru Takahashi, Terumo Medical Corporation, USA
Structural Modification of the Alpha-helicalAntimicrobial Brevinin-2 Related Peptide – A Comparison Study of Biosimilars
Siqin Liu, Queen's University Belfast, UK
Ultra performance liquid chromatography mass spectrometric analysis for rapid quantitation of isoquinoline alkaloids in Thalictrumreniforme
Vikas Bajpai, Central Drug Research Institute, India
Cold active endo-glucanase from Antarctic Yeast, Glaciozyma antarctica PI12; expression and characterisation
Salimeh Mohammadi, University Kebangsaan Malaysia, Malaysia

Day 3 October 28, 2015

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
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
Prevention potency of soaps and disinfectants on Vancomycin resistant Enterococcus faecalis infection
Adetunji Olawale, Osun State Polytechnic, Nigeria
Bioanalytical challenges of biosimilar development; making you wish you had a mirror to put in front of the innovator drug
Afshin Safavi, BioAgilytix, USA
Protein binding drug-drug interaction
Mariana Babayeva, Touro College of Pharmacy, USA
The characterisation of biosimilar mAbs using biologically relevant and sensitive ADCC methodologies
Andy Upsall, BioOutsorce, UK
Development of a biosimilar CMC strategy for the identification of critical quality attributes
Samantha Little, Covance Laboratories, UK
Characterization of Glatiramer acetate C-terminal heterogeneity
Mario DiPaola, Bluestream Lab., USA

Closing & Award ceremony

Day 1 October 27, 2014

Keynote Forum

Nigel Rulewski
Quintiles Inc., USA

Mohan Dewan
R.K. Dewan & Co., India

Steven Lehrer
Cipla Ltd., USA

Heike Schon
LUMIS International GmbH, Germany

Title: 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
Title: Biosimilar regulations in the ASEAN
Shivraj Dasari, SLS Cell Cure Technologies Pvt. Ltd., India
Title: Challenges in demonstrating biosimilarity and interchangeability of biosimilar products
Rodeina Challand, PRA Health Sciences, UK
Title: Comparison of US/EU biosimilar guidelines
Kamali Chance, Quintiles Inc., USA
Title: Challenges and its resolutions in the conduct of biosimilars clinical development
Chirag Shah, Cliantha Research Ltd., India
Title: Being-similar: From benchside to bedside
Manish Mahajan, Lupin Ltd., India
Title: Quality attributes of biologic products and standard setting process – USP perspective
Ranjan Chakrabarti, United States Pharmacopeia India Pvt. Ltd., India
Title: Emerging trends and biosimilars regulation in India
R Manavalan, Annamalai University, India
Title: Emerging trends in biosimilars and biologics
Kaiser Jamil, Bhagwan Mahavir Medical Research Centre, India
Title: Potential value of biosimilars- will biosimilars be cost effective compared to the branded equivalents?
Shabana Khan, Ecron Acunova, India
Title: 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

Workshop

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

Symposium

Title: Biosimilars and their prospective future in the market
Murali Bukkapatnam, TiE, India

Day 2 October 28, 2014

Keynote Forum

Krishna Menon
Cellceutix Corporation, USA

Rodeina Challand
PRA Health Sciences, UK

Title: Biological and functional characterization of anti-TNFα biosimilar durgs
Daniel Galbraith, BioOutsource Ltd., UK
Title: Evaluation of immunogenicity in biotherapeutics
Surendra J Chavan, Quantimmune Solutions Pvt. Ltd., India
Title: Commercial opportunities in biosimilars
Steve Lehrer, Cipla Ltd., USA
Title: Plant derived cyclopolypeptides: Targets for drug discovery
Rajiv Dahiya, Association of Pharmacy Professionals, India
Title: Risk assessment: A pragmatic approach to develop biosimilars
Harish Shandilya, INTAS Biopharmaceuticals Ltd., India
Title: Successful conduct of clinical trials to prove biosimilarity by defining a best fit outsourcing strategy
Heike Schoen, LUMIS International GmbH, Germany
Title: Intas–Merck Millipore: Partnership in biosimilars development strategy for emerging markets
Jennifer Campbell, Merck Millipore, France **& Shalini Sharma,** Intas Pharmaceuticals Ltd, India
Title: Enzyme engineering: An innovative way to manage the economics of biosimilars- Polyclone case study
Naveen Kulkarni, Polyclone Bioservices Pvt. Ltd., India
Title: Roadmap of stability studies for biosimilar product development
Rashbehari Tunga, Stelis Biopharma, India
Title: Future of next generation biosimilars
Kamlesh Patel, Abbott HealthCare Pvt. Ltd., India

Title: Clinical development of biosimilars: Overcoming challenges
Charu Manaktala, Quintiles Inc., India
Title: Challenges faced in the development of biosimilars
Hima Bindu Gujjarlamudi, Rajiv Gandhi Institute of Medical Sciences (RIMS), India
Title: Clinical trials of biosimilars in developing nations: obstacles and opportunities
N Srinivas, Malla Reddy Institute of Pharmaceutical Sciences, India
Title: Best practices for high concentration ultrafiltration applications
Subhasis Banerjee, Merck Millipore, India
Title: Bioanalytical strategy for biosimilars: Recommended steps for establishment of comparability
Aparna Kasinath, Clinigene International Ltd., India
Title: Understanding osteomyelitis and its solution through cost effective biomaterial based strategies
Samit Kumar Nandi, West Bengal University of Animal and Fishery Sciences, India
Title: Virus filtration for biosimilar manufacturing: from needs to solutions
Tathagata Ray, Merck Millipore, India
Title: An alternate approach for sialic acid estimation in erythropoietin by HPAEC-PAD method
R Jayachandran, United States Pharmacopeia India Pvt. Ltd., India
Title: Analytical biosimilarity: Strategies and challenges
Shalini Sharma, Intas Pharmaceuticals Ltd., India
Title: Alternate approaches addressing variability in ADCC assay
Prabhavathy Munagala, United States Pharmacopeia India Pvt. Ltd., India

` Presentations @ Hall 4

Day 3 October 29, 2014

Title: Biosimilars in the United States–Update on FDA implementation and other current issues
James C Shehan, Hyman, Phelps & McNamara, USA
Title: The positive role of intellectual property in the creation of cost effective and affordable biosimilars
Mohan Dewan, R.K. Dewan & Co., India
Title: IP checklist for similar biologics
Mita Sheikh, Krishna & Saurastri Associates, India
Title: Patent issues in biopharmaceutical industry
Vijay Kumar, BioBridge Healthcare Solutions Pvt. Ltd., India
Title: 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

Title: Patenting of biosimilars in India and related issues
Vijay Kumar Makyam, IP Markets, India
Title: Compulsory licensing: A delicate balance between biosimilars and innovations
Poongothai A R, IP Markets, India
Title: Challenges for biosimilar generics
Vivek Kashyap, Lex Orbis IP Practice, India
Title: Preparing for U.S. market entry–strategy considerations in view of BPCIA and AIA
Renita S Rathinam, Sughrue Mion PLLC, USA

Title: Biosimilars: Globalization of biosimilars
Ravi R Ghanghas, Govt. Medical College, India
Title: A next generation sequencing approach drives target personalized therapy of acute myeloid leukemia
Giovanni Martinelli, Bologna University School of Medicine, Italy
Title: Host cell protein and other impurity clearance assays for biosimilar development
Arumugam Muruganandam, Affigenix Biosolutions Pvt. Ltd., India

Title: Safety concerns related to global biosimilars drug development
Nigel Rulewski, Quintiles Inc., USA
Title: Pharmacovigilance of biosimilars: Challenges & possible solutions
J Vijay Venkatraman, Oviya MedSafe, India
Title: Role of pharma industries in the improvement of pharmacovigilance system
Kamlesh Patel, Abbott HealthCare Pvt. Ltd., India
Title: Synergism of 'nutraceutical' and 'pharmaceutical' for safety
Ekta K Kalra, Ekta K Kalra Writing Company, India
Title: The key roles & responsibilities of pharmacists in biosimilars development
N Srinivas, Malla Reddy Institute of Pharmaceutical Sciences, India

Panel Discussion: 15:40-15:45

Young Researcher Forum

Title: Bimodal gastroretentive drug delivery systems of lamotrigine: Formulation and evaluation
Rajasekhar Reddy Poonuru, St. Peter's Institute of Pharmaceutical Sciences, India
Title: Dissolution testing of nicotinamide cocrystals of a model BCS Class-II drug
Kale Mohana Raghava Srivalli, IIT (BHU), India

Title: Medication usage and nutritional status in hemodialysis
S Chan Mubeena, Sri Padmavathi Mahila Viswavidyalayam, India
Title: Combined approach of biosimilar trastuzumab monoclonal antibody with nanoparticles targeted to prostate tumor cells
Dubey Satendra Kumar, JSS University, India
Title: Effect of lipid digestion media on the fate of drug in lipid based nanoemulsion
R Suresh Kumar, JSS University, India
Title: Design and synthesis of some novel antibacterial agents targeting Gyrase B and Par E
Janarthanan T, JSS University, India

Posters Presentation @ Hall 4

Title: The quest for cost effective treatment in rheumatoid arthritis: Are biosimilars the right choice?
Phani Kishore Thimmaraju, Phamax Market Access Solutions, India
Title: *In vivo* characterization of snail extract loaded marine biomaterials in bone regeneration
Piyali Das, West Bengal University of Animal and Fishery Sciences, India
Title: Effect of curcumin in celecoxib and streptozotocin induced experimental dementia of Alzheimer disease in mice
Ahsas Goyal, DGLA University, India
Title: Recombinant version of streptokinase: An overview
Alice Jaya Pradha Cheekurthy, Acharya Nagarjuna University, India
Title: Demonstration of multivariate data analysis for the development of *Boswellia serratta* plant extracts containing nanoemulsion
Mukesh Gohel, Anand Pharmacy College, India
Title: Development and evaluation of digestive enzyme formulations
Chaudhari Nilesh B, Sandip Institute of Pharmaceutical Sciences, India
Title: Serotonin storm- A drug induced syndrome
Lilli Sailaja G, Doctor of Pharmacy Association, India
Title: Global perspectives and future implications of biosimilars in next generation treatment
Jemy Rajan, Doctor of Pharmacy Association, India

Title: Survey of US certified diabetes educators (CDEs) suggests high interest in future use of biosimilar insulin due to cost savings
Jessica Dong, Close Concerns Inc., USA
Title: Drug release kinetics in polymeric delivery systems
M Vani, Doctor of Pharmacy Association, India
Title: The challenge of tuberculosis to the global public health care: A clinical pharmacist perspective
Khadeer Ahmed Ghori, Doctor of Pharmacy Association, India
Title: The Indian pharmaceutical industries should support dichloroacetate (DCA): A new potential metabolic-targeting drug available at low price for cancer treatment
M Manasa Rekha, Doctor of Pharmacy Association, India
Title: The omega-3 fatty acids serves as alternate safe new pharmacological treatment for cardio vascular diseases which effectively decreases the mortality
M Navya Sree, Doctor of Pharmacy Association, India
Title: Investigation of actual chemical constituents and anti-inflammatory activity of Arka leaves extracts
Mohammed Rageeb Mohammed Usman, Smt. Sharadchandrika Suresh Patil College of Pharmacy, India
Title: Drug discovery: Though chemi-bioinformatics-from system to market
M Murali Mohan Gutti, JNTU, India
Title: Monitoring adverse drug reaction of various pharmaceutical products in rural population of South India
Stefin Mary Mathew, Doctor of Pharmacy Association, India
Title: Antihypertensive effect of leaves of *Tephrosia purpurea* Linn. on isolated frog heart
Sufiyan Ahmad, Gangamai College of Pharmacy, India
Title: Development of validated analytical method for risperidone in pharmaceutical solid dosage form by HPTLC
Sunil Singh, Mewar University, India

Title: Synthesis and pharmacological screening of some benzimidazole derivatives
Sunila T Patil, P.S.G.V.P.M's College of Pharmacy, India
Title: Acceptance of biosimilar products in the treatment of rheumatoid arthritis
Narendra Kumar Vemulapalli, Doctor of Pharmacy Association, India
Title: Development and validation of RP-HPLC method for simultaneous estimation of cefixime and cloxacillin from tablet dosage-form
Wankhede Ajit R, Sandip Institute of Pharmaceutical Sciences, India
Title: Risk of stroke in smokers
B Jyothi, Doctor of Pharmacy Association, India
Title: Over the counter drugs - Advantages and risks of self-management of OTC drugs in older adult patients
B Neelima, Doctor of Pharmacy Association, India
Title: Neuroleptic malignant syndrome - A neuroleptic induced syndrome
K V Jagadeesh, Doctor of Pharmacy Association, India

Title: Evaluation of behavioural studies of *Linum usitatissimum*
R Naga Kishore, Geethanjali College of Pharmacy, India
Title: Cefpodoxime proxetil gastroretentive effervescent floating tablets by using various hydrophilic polymers
M Naga Ganesh, Geethanjali College of Pharmacy, India

Title: Development and validation of UV- spectrophotometric simultaneous equation method for simvastatin and ezetimibe in tablet formulation
Murtadak Sagar N, Sandip Institute of Pharmaceutical Sciences, India
Title: Bioanalysis of riluzole in human plasma by a sensitive LC-MS/MS method and its application to a pharmacokinetic study in South Indian subjects
Anjaneyulu Narapusetti, Geethanjali College of Pharmacy, India
Title: Pharmaceutical care program educate patient on quality of life (QOL) in type2 diabetes mellitus in Dhule
Tabrej Mujawar, R. C. Patel Institute of Pharmaceutical Education & Research, India
Title: Extraction and characterization of gum from *Lepidium sativum* Linn. and *Cordia dichotoma* Linn. for its film forming properties and studies about release characteristic of these films
Vaibhav M Darvhekar, P. Wadvani College of Pharmacy, India
Title: Biosimilars-destination in India
J Sadhana Reddy, Anurag Group of Institution, India
Title: Liquisolid technique for dissolution enhancement of hormones belonging to BCS Class II
Sameer Nadaf, Bharati Vidyapeeth College of Pharmacy, India
Title: New visible spectrophometric methods for the assay of spiramycine
Karteek Rao Amperayani, GITAM University, India
Title: Pharmacognostic studies, bianthraquinones and spermidine alkaloid from *Cassia floribunda*
Podila Venu, The University of Greenwich, UK
Title: Search for effective antimycotic agents against *Microsporum gypseum* from 61 ethno medicinal plants of Hyderabad Karnataka region, India
Shivakumar Singh P, Gulbarga University, India
Title: Current problems and future aspects of pharmacovigilance in india
Pragnya Devi U, Doctor of Pharmacy Association, India

Title: Synthesis and biological activity of a cyclic hexapeptide from *Dianthus superbus*
Suresh Beniwal, Kurukshetra University, India
Title: Potential role of pharma-industries in addressing the challenges in pharmacovigilence: Practice changes & outcome trends
Malawika Maheswari K, Doctor of Pharmacy Association, India
Title: Anti-cancer biosimilars from natural products
P V Lalith, Gurunanak Institute of Pharmacy, India
Title: Assessment of knowledge, adherence and attitude of patients towards tuberculosis, its medications and effect of counselling in a medical college outpatient clinic
Syeda Sumayya Siraj, Deccan School of Pharmacy, India
Title: Cost-effectiveness and pharmacoeconomic analysis of combined inhaled corticosteroids and brochodilators for severe and very severe COPD patients and health related quality of Life of COPD patients in a teaching hospital
Mohammed Altaf, Deccan School of Pharmacy, India
Title: Synthesis and antimicrobial screening of 1, 2, 4 H-triazole derivatives
Neha Yadav, VNS Faculty of Pharmacy, India
Title: *Agrobacterium*-mediated genetic transformation of tobacco cells and annexin gene cloning using pTZ57R/T vector
Jithender D, Osmania University, India