

11<sup>th</sup> European

# Biosimilars Congress

April 26-27, 2018 | Rome, Italy



Olimpica 2

conference**series**.com 10:00-10:20

# Opening Ceremony

## Keynote Forum

- 10:20-10:30 **Introduction**  
Title: **The glycosylation aspects of biosimilarity**  
10:30-11:00 **Andras Guttman, SCIEX, USA**

## Group Photo 11:00-11:05

## Networking and Refreshments Break 11:05-11:20 @ Foyer

- 11:20-11:50 **Title: Establishing finger-print like biosimilarity: Critical characterization steps for biosimilar assessment**  
**Fiona M Greer, SGS Life Sciences, Switzerland**  
11:50-12:20 **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**

**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**

**Session Chair: Sakae Tsuda, National Institute of Advanced Industrial Science and Technology, Japan**

**Session Chair: Kamali Chance, BioSciencesCorp, USA**

## Session Introduction

- 12:20-12:40 **Title: Application of new quality products of type I-III antifreeze proteins and antifreeze glycoprotein**  
**Sakae Tsuda, National Institute of Advanced Industrial Science and Technology, Japan**  
12:40-13:00 **Title: Technical challenges in developing biosimilar antibodies**  
**Emile Van Corven, Bioceros, Netherlands**

## Lunch Break 13:00-13:50 @ Hotel Restaurant

- 13:50-14:10 **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**  
14:10-14:30 **Title: Bioanalytical methods for biosimilars: An approach**  
**R Helena Bustos-Cruz, Universidad de La Sabana, Colombia**  
14:30-14:50 **Title: The Bio Immune(G)ene medicine and the use of miRNAs to regulate the cell**  
**M. Carme Parés Santilari, European Bio Immune(G)ene Medicine Association, France**  
14:50-15:10 **Title: Biosimilars in the United States: A progress report and a peek in to the future**  
**Kurt R Karst, Hyman, Phelps & McNamara, PC., USA**  
15:10-15:30 **Title: How to meet FDA requirements for demonstration of interchangeability?**  
**Kamali Chance, BioSciencesCorp, USA**  
15:30-15:50 **Title: Automated permethylation for glycosylation analysis of biologics using MALDI-TOF-MS**  
**Archana Shubhakar, Ludger Ltd, UK**

## Networking and Refreshments Break 15:50-16:05 @Foyer

- 16:05-16:25 **Title: Getting the NHS ready for the biosimilar boom: Shifting attitudes, acceptance and appetites**  
**Theo Christie, National Institute for Health Research, UK**  
16:25-16:45 **Title: "In the name" of biosimilars: Trademarks issues**  
**Roberto Valenti, DLA Piper, Italy**  
16:45-17:05 **Title: An *in-vitro* functional assessment of a biosimilar rituximab and its originator**  
**Fatemeh Torkashvand, Pasteur Institute of Iran, Iran**

17:05-17:25 **Title: Biosimilar uptake in the MENA region: Strategies and challenges**  
Yazan Shaban, Hikma Pharmaceuticals, Jordan

**Panel Discussion**

**Day 2 April 27, 2018**

**Olimpica 2**

**Keynote Forum**

10:00-10:10 **Introduction**

**Title: Toolbox needed for structural characterization and comparability studies of glycan biosimilars**

10:10-10:40

Parastoo Azadi, Complex Carbohydrate Research Center - University of Georgia, USA

**Title: Optimizing clinical trials as part of the totality of data to support the marketing approval of biosimilars**

10:40-11:10

Cecil Nick, PAREXEL International, UK

**Networking and Refreshments Break 11:10-11:25 @ Foyer**

11:25-11:55 **Title: Biosimilars in Europe: Is there a golden rule to pricing?**  
Dominic Seitz, Simon-Kucher & Partners, Germany

**Poster Presentations 11:55-12:30**

**Poster Judge: Andras Guttman, SCIEX, USA**

**Poster Judge: David Ebsworth, Vifor Pharma Ltd, Switzerland**

EBC01 **Title: CHO expression platform technology for cell line development of biosimilars**  
Cornelia Lindner, Sartorius Stedim Cellca GmbH, Germany

EBC02 **Title: Mechanism of Action (MOA): Reflecting bioassays for biosimilar drug development**  
Steven Edenson, Promega, USA

EBC03 **Title: Biologics in autoimmune disease**  
Sandra Šimić, Ewopharma d.o.o, Croatia

EBC04 **Title: Detection of diverse virulence factors in phages Methicillin Resistance *Staphylococcus Aureus*(MRSA) Isolated from mastitic cows**  
Atheer Abdulrazzaq Abdulazeez, University of Baghdad, Iraq

**Lunch Break 12:30-13:20 @ Hotel Restaurant**

**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**

**Session Chair: Roberta Bursi, InsilicoTRIALS, Italy**

**Session Chair: Oleksandr Kukharchuk, ReeLabs Pvt. Ltd., India**

**Session Introduction**

13:20-13:40 **Title: *InsilicoTRIALS* democratizes simulations in healthcare**  
Roberta Bursi, InsilicoTRIALS, Italy

13:40-14:00 **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 RAS, Russia

14:00-14:20 **Title: Identification of biosimilarity in early process development and clone screening**  
Thomas Zahel, Exputec GmbH, Austria

14:20-14:40 **Title: Analysis of the pharmacological intervention and cognitive development through technology in the treatment of autism**  
Eraldo Martins Guerra Filho, Recife Center for Advanced Studies and Systems, Brazil

14:40-15:00 **Title: Influence of fetal placenta extract on growth of experimental solid tumors**  
Oleksandr Kukharchuk, ReeLabs Pvt. Ltd., India



**15:00-15:20** Title: **Innovative, cost effective solution for self-administration of bio-similar drugs**  
Menachem Zucker, E3D Elcam Drug Delivery Devices, Israel

**15:20-15:40** Title: **Meeting the challenges of gaining marketing approval of biosimilars across the globe**  
Cecil Nick, PAREXEL International, UK

**Networking and Refreshments Break 15:40-15:55 @ Foyer**

**15:55-16:15** Title: **Using organ-specific progenitor cells extracts in regenerative medicine**  
Padma Priya Anand Baskaran, ReeLabs Pvt. Ltd., India

**16:15-16:35** Title: **Applications and advantages of gold nanoparticles as X-ray contrast agent**  
Mohammed H Alwan, Al Nahrain University, Iraq

**16:35-16:55** Title: **Understanding the nocebo effect that can help in optimizing treatment outcomes with biosimilars**  
Mourad F Rezk, Medical and Scientific Affairs, Switzerland

**Video Presentation**

**16:55-17:15** Andrei Lamsters, Estonia

**Panel Discussion**

**Awards & Closing Ceremony**



**Bookmark your dates**

# 12<sup>th</sup> European Biosimilars Congress

April 15-16, 2019 Berlin, Germany

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