

JOINT EVENT

Proceedings of

13th International Conference on

BIOLOGICS AND BIOSIMILARS & BIOPHARMA & BIOTHERAPEUTICS

October 24-25, 2018 | Boston, USA



Day 1 October 24, 2018

Conference Hall: Parker Boardroom

08:15-09:00 Registrations

09:00-09:10 Opening Ceremony

Keynote Forum

09:10-09:15 Introduction

09:15-09:45 Title: The end of clinical trials in biosimilars development?

Francois Xavier Frapaise, Biosimilars Consultant Paris, France

09:45-10:15 Title: Development of biologics and biosimilars in emerging markets – Challenges example Brazil

Peter H Kalinka, Longmore 60 Biotech, USA

10:15-10:45 Title: The influence of nanomedicine on drug discovery

Thomas J Webster, Northeastern University, USA

Panel Discussion & Group Photo

Networking & Refreshment Break 10:45-11:00 @ Foyer

11:00-11:30 Title: E-BABE: How to address immunogenicity in the development of a rare disease biosimilar
Candida Fratazzi, Bull Breed Coalition Registry Consulting, USA

11:30-12:00 Title: Latest developments in biopharma's patient-centric drug development paradigm:
How to leverage these opportunities and maximize innovation

Leigh Ann M Durant, EMD Serono, Inc., USA

12:00-12:30 Title: FDA's expedited testing and approval: Fast tracking drug approval-What does it take to qualify?

Aruna Dontabhaktuni, PharmaPro Consulting Inc., USA

Panel Discussion

Lunch Break 12:30-13:30 @ Bistro

Sessions: Current Challenges in Developing Biosimilars | Clinical Development of Biosimilars | Biosimilars Analytical Strategies | Biosimilars Companies and Market Analysis | Current Trends in Pharmaceutical Industries | Challenges in Biosimilars Pharmacovigilance

Session Chair: Peter H. Kalinka, Longmore 60 Biotech Inc., USA

Session Introduction

13:30-13:50 Title: Risk based development and manufacturing of biosimilars
Neil Schauer, Schauer Biologics Consulting LLC, USA

13:50-14:10 Title: Using SPOT™ and SLIM™ technology in our CHO^{BC}® platform to reduce cost of goods of biosimilars

Louis Boon, Bioceros BV, Poland

14:10-15:10 Title: Packaging challenge for biosimilar products

Anupam Chanda, Alembic Pharmaceuticals Ltd, India

15:10-15:30 Title: Biosimilars analytical strategies

Sung Nyeo Shim, Chong Kun Dang Pharmaceuticals, South Korea

Panel Discussion

Networking & Refreshment Break 15:30-15:50 @ Foyer

15:50-16:10 Title: Understanding the market access landscape for biosimilars
Anita Burrell, Health Strategies Group, USA

16:10-16:30 Title: How to start a biosimilar development: A risk based approach

Karlheinz Landauer, Quality Biotech Development & Cells GmbH, Switzerland

Special Session (Panel Discussion)

16:30-17:30 Title: **Biosimilars: A new form of social contract**

Session Chair: Francois Xavier Frapaise, Biosimilars Consultant Paris, France

Panelist: Neil Schauer, Schauer Biologics Consulting, LLC, USA

Panelist: Ha Kung Wong, Fitzpatrick, Cella, Harper & Scinto, US

Panelist: Joel I Osorio, RegenerAge SAPI de CV, Mexico

Panel Discussion

Day 2 October 25, 2018

Conference Hall: Parker Boardroom

Keynote Forum

09:00-09:15 Introduction

09:15-09:45 Title: **“Why so serious?” – The increasing impact of post grant challenges to biologics and biosimilars in the US**

Ha Kung Wong, Fitzpatrick, Cella, Harper & Scinto, US

09:45-10:15 Title: **Where the US biosimilars market is going and when it might get there**

Stanton R Mehr, Biosimilars Review & Reports, USA

10:15-10:45 Title: **Enabling a global collaborative ecosystem in the realm of biopharma**

Himabindu Gaddipati, Elixsys Inc., USA

Panel Discussion & Group Photo

Networking & Refreshment Break 10:45-11:00 @ Foyer

Sessions: **Regulatory Approach for Biosimilars | Globalization of Biosimilars | Biosimilars Research Pipeline | Analytical Characterization of Biotherapeutics | Biopharmaceutical Regulatory Affairs**

Sessions Chair: Leigh-Ann M. Durant, EMD Serono, Inc., USA

11:00-11:20 Title: **Transformations in global pharmaceutical industry**

Nitin Naik, Frost and Sullivan, USA

11:20-11:40 Title: **Health plan perspective: Assuring a vibrant and competitive marketplace for biosimilars**

Gregory Gierer, America's Health Insurance Plans, USA

11:40-12:00 Title: **Market access barriers and market value in Mexican public sector for biosimilars**

Jose Carlos Ferreyra Lopez, The Pharmaceutical Institute, Mexico

12:00-12:20 Title: **Regenerage system: Therapeutic effects of combinatorial biologics (mRNA and allogenic MSCs) with a spinal cord stimulation system on a patient with spinal cord section**

Joel I Osorio, RegenerAge SAPI de CV, Mexico

Young Researchers Forum

12:20-12:40 Title: **Microfluidics: An advanced platform for pharmaceutical protein formulation**

Sabiruddin Mirza, Harvard University, USA

Panel Discussion

Lunch Break 12:40-13:40 @ Bistro

Workshop

13:40-14:40 Title: **Process development with CHO and hybridoma cell lines: Differences, challenges, things to know**

Peter H Kalinka, Longmore 60 Biotech Inc., USA &

Robert Swift, Invenux, LLC Windsor, USA

Video Presentation

14:40-14:45 Title: **Ibn el-bitar project**

Sakina Benabdelkader, Abou Bekr Belkaid University, Algeria

Networking (1-1 Meeting) 14:45-15:45

Networking & Refreshment Break 15:45-16:00 @ Foyer

Thanks Giving & Closing Ceremony