Scientific Program

Day 1 - October 24, 2018

8:00-8:45	Registrations
8:45-8:55	Opening Ceremony
	Keynote Presentations
08:55-09:00	Introduction
09:00-09:30	Title: The End of Clinical Trials in Biosimilars Development
	Francois Xavier Frapaise, Frapaise Consulting, France
09:30-10:00	Title: Development of Biologics and Biosimilars in emerging Markets – Challenges Example Brazil
	Peter H. Kalinka, Longmore 60 Biotech, USA
10:00-10:30	Title: The Influence of Nanomedicine on Drug Discovery
	Thomas J. Webster , Northeastern University, USA
	Group Photo 10:30-10:40
	Panel Discussions
	Coffee Break 10:40-11:00
11:00-11:30	Title: E-BABE: How to address immunogenicity in the development of a rare disease biosimilar
	Candida Fratazzi, BBCR 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
12:30-13:00	Title: FDA's expedited testing and approval: Fast tracking drug approval-what does it take to qualify?
	Aruna Dontabhaktuni, PharmaPro Consulting Inc., USA
	Lunch Break 13:00-14:00
	Session Introduction
	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 Introduction
	Sessions Chair: Peter H. Kalinka
14:00-14:20	Title: Risk Based Development and Manufacturing of Biosimilars
	Neil Schauer, Schauer Biologics Consulting, LLC, USA
14:20-14:40	Title: Using SPOT™ and SLIM™ technology in our CHOBC® platform to reduce cost of goods of biosimilars
	Louis Boon, Bioceros, Netherlands
14:40-15:40	Title: Packaging Challenge for Biosimilar Products
	Anupam Chanda, Alembic Pharmaceuticals Ltd, India
	Networking Break 15:40-16:00
16:00-16:20	Title: Biosimilars Analytical Strategies
	Sung Nyeo, CKD Pharmaceuticals, South Korea
16:20-16:40	Title: Understanding the market access landscape for Biosimilars
	Anita Burrell, Health Strategies Group, USA

16:40-17:00	**Title: How to start a Biosimilar development: A risk based approach**
	Karlheinz Landauer, Quality Biotech Development & Cells GmbH, Germany
Panel Discussions	
17:00-18:00	**Title: Biosimilars: A new form of Social Contract**
	Panelists
	Panel Chair: Francois Xavier Frapaise, Frapaise Consulting, France
	Neil Schauer, Schauer Biologics Consulting, LLC, USA
	HaKung Wong, Fitzpatrick, Cella, Harper & Scinto, USA
	Joel I. Osorio, RegenerAge Clinic, USA
	Day 1 Concludes
Day 2 - October 25, 2018	
Keynote Presentations	
8:30-8:40	**Introduction**
8:40-9:10	**Title: "Why So Serious?" – The Increasing Impact of Post Grant Challenges to Biologics and Biosimilars in the US**
	HaKung Wong, Fitzpatrick Cella Harper & Scinto, USA
9:10-9:40	**Title: Where the US Biosimilars Market Is Going and When It Might Get There**
	Stan Mehr, Payer Markets and Biosimilars Industry, USA
9:40-10:10	**Title: Enabling a global collaborative ecosystem in the realm of biopharma**
	Himabindu Gaddipati , Clinical Trials of Texas, USA
Session Introduction	
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	
10:10-10:30	**Title: TBA**
	Nitin Naik, Global Life Sciences at Frost & Sullivan, USA
Panel Discussions	
Coffee Break 10:30-10:50	
10:50-11:10	**Title: Health Plan Perspective: Assuring a Vibrant and Competitive Marketplace for Biosimilars**
	Gregory Gierer, America's Health Insurance Plans , USA
11:10-11:30	**Title: Biosimilars Market in Mexico**
	Jose Carlos Ferreyra, Harvard Medical School, USA
11:30-11:50	**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
Workshop	
11:50-12:50	**Title: Process development with CHO and hybridoma cell lines: Differences, Challenges, things to know**
	Dr. Peter H Kalinka and Dr. Robert Swift
Lunch Break 12:50-13:50	
13:50-14:10	**Title: The issues of pharmaceutical industry for the workers at workplace: A Case Study**

	Abdullah Ellahi, Aqmar pharmaceutical private limited, Pakistan
14:10-14:30	Title: Microfluidics: An advanced platform for pharmaceutical protein formulation
	Sabiruddin Mirza, Harvard University, USA
14:30-14:50	Title: Process validation and critical regulatory requirements in manufacturing of inactivated veterinary vaccines
	Ahmed Hesham, Middle East for Veterinary Vaccine, Egypt
Video Presentation Session	
14:50-15:10	Title: Title: Ibn El-Bitar Project
	Sakina Benabdelkader
Panel Discussions	
Networking Break 15:30-16:15	
Networking (1-1 Meeting)	
Closing Cermony	