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Scientific Program

5th European Biosimilars Congress

June 27-29, 2016 Valencia, Spain



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Scientific Program

Day 1 June 27, 2016

08:30-09:00 Registrations

Melia Meeting 1+2

conferenceseries.com **09:00-09:30** **Opening Ceremony**

Keynote Forum

09:30-09:45 **Introduction**

09:45-10:30 **Interchangeability of biological drug products**
Laszlo Endrenyi, University of Toronto, Canada

10:30-11:15 **Evaluating immunogenicity biosimilars**
Candida Fratazzi, BBCR Consulting, USA

Group Photo

Networking and Refreshments: 11:15-11:35 @ Foyer Business Center

12:20-13:05 **FDA/EMA Current thinking on totality of evidence for biosimilar approvals**
Kamali Chance, Quintiles Inc., USA

Lunch Break: 13:05-14:10 @ Aqua Restaurant

Sessions:
Track 2: Emerging Biosimilar in Therapeutics
Track 8: Clinical Studies on Biosimilars

Session Introduction

14:10-14:40 **Supporting biosimilar clinical trials in the UK**
Sarah Cooper, National Health Service , UK

14:40-15:10 **The emergence of orphan Biosimilars**
Triona Bolger, Navigant Consulting, Inc, UK

Sessions:
Track 1: Current Challenges of Biologics
Track 4: Regulatory Approach for Biosimilars
Track 5: Legal Issues
Track 9: Intellectual Property Rights

Session Introduction

Session Chair: Paul A Calvo, Sterne, Kessler, Goldstein & Fox, USA

15:15-15:45 **The importance of IP protection and SPCs for biologics and biosimilar products**
Luder Behrens, Boehmert & Boehmert, Germany

Networking and Refreshments: 15:45-16:15

16:15-16:45 **An update on the legal landscape for biosimilars in the USA**
Paul A Calvo, Sterne, Kessler, Goldstein & Fox, USA

16:45-17:15 **Intellectual Property Issues in global biosimilar programs**
Christoph Volpers, Michalski Hüttermann & Partner, Germany

17:15-17:45 **Dosing, double patenting and the US biosimilars landscape**
Nabeela Rasheed, McAndrews, Held & Malloy, Ltd, USA

Panel Discussion

Day 2 June 28, 2016

Melia Meeting 1+2

Keynote Forum

09:00-09:45 **Startegies for biosimilars development**
Andreu Soldevila, LeanBio Pro, Spain

09:45-10:30 **Establishing "Finger-print like" biosimilarity-Critical characterization steps for biosimilar assessment.**
Fiona M Greer, SGS Life Sciences, Switzerland

Networking and Refreshments: 10:30-10:55 @ Foyer Business Center

Sessions:
Track 3: Biosimilar Analytical Strategies
Track 10: Bioequivalence Assessment
Track 13: Biosimilar Pharmacovigilance

Session Introduction

Session Chair: Andreu Soldevila, LeanBio Pro, Spain

10:55-11:25 **Biosimilar development cost: Role of analytics**
Dipti Gulati, PJI Biotech, USA

11:25-11:55 **Pharmacovigilance in cancer medicine**
Luis H Camacho, Center for Oncology and Blood Disorders, Houston, USA

11:55-12:25 **Process Raman Spectroscopy for in-Line monitoring of mammalian cell cultures in real time**
Alexander Pitters, Kaiser Optical Systems, SARL, France

12:25-12:55 **Analytical assessment of biosimilarity – Considerations in study design**
Christina Vessely, Biologics Consulting, USA

Lunch Break: 12:55-14:00 @ Aqua Restaurant

14:00-14:45 **Overcoming the challenges of biosimilar development as a mid-size player**
Ruediger Jankowsky, Cinfa Biotech, Germany

14:45-15:15 **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

Sessions:
Track 6: Biosimilar Innovator Pharmaceutical Products
Track 7: Globalization of Biosimilars
Track 11: BCS & IVIVC Based Biowaivers
Track 12: Biosimilar Market Analysis

Session Introduction

Session Chair: Christelle Dagoneau, Catalent Biologics, USA

15:15-15:45 **Impact on technology integration on better and faster Biosimilars pipeline**
Christelle Dagoneau, Catalent Biologics, USA

15:45-16:15 **Biosimilar Globalization- A silver lining in untested waters**
Candida Fratazzi, BBCR Consulting, USA

Networking and Refreshments: 16:15-16:40 @ Foyer Business Center

16:40-17:10 **From neuronal networks to neuromodulation with biosimilars**
Luis Ulloa, Rutgers-New Jersey Medical School, USA

17:10-17:40 **High throughput assays for the determination of the potency and comparability of Biosimilars and innovator products**
Michael G Tovey, INSERM, France

17:40-18:10 **Growth potential of Biosimilar products in Bangladesh**
Md. Abu Zafor Sadek, Renata Ltd., Bangladesh

Poster Presentations

Panel Discussion

Award Ceremony

Day 3 June 29, 2016

Extended Networking Sessions and Lunch: 12:00-13:00



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