Scientific Program

5th European Biosimilars Congress

June 27-29, 2016   Valencia, Spain
## Scientific Program

### Day 1  June 27, 2016

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>08:30-09:00</td>
<td>Registrations</td>
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<tr>
<td>09:00-09:30</td>
<td>Opening Ceremony</td>
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<tr>
<td>09:30-09:45</td>
<td>Introduction</td>
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<td>09:45-10:30</td>
<td>Interchangeability of biological drug products&lt;br&gt;Laszlo Endrenyi, University of Toronto, Canada</td>
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<td>10:30-11:15</td>
<td>Evaluating immunogenicity biosimilars&lt;br&gt;Candida Fratazzi, BBCR Consulting, USA</td>
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<td>10:30-11:15</td>
<td>Group Photo</td>
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<td>12:20-13:05</td>
<td>FDA/EMA Current thinking on totality of evidence for biosimilar approvals&lt;br&gt;Kamali Chance, Quintiles Inc., USA</td>
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<td>12:20-13:05</td>
<td>Lunch Break: 13:05-14:10 @ Aqua Restaurant</td>
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### Sessions:

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

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<th>Time</th>
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<tr>
<td>14:10-14:40</td>
<td>Supporting biosimilar clinical trials in the UK&lt;br&gt;Sarah Cooper, National Health Service, UK</td>
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<td>14:40-15:10</td>
<td>The emergence of orphan Biosimilars&lt;br&gt;Triona Bolger, Navigant Consulting, Inc, UK</td>
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<td>15:15-15:45</td>
<td>The importance of IP protection and SPCs for biologics and biosimilar products&lt;br&gt;Luder Behrens, Boehmert &amp; Boehmert, Germany</td>
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<td>16:15-16:45</td>
<td>An update on the legal landscape for biosimilars in the USA&lt;br&gt;Paul A Calvo, Sterne, Kessler, Goldstein &amp; Fox, USA</td>
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<td>16:45-17:15</td>
<td>Intellectual Property Issues in global biosimilar programs&lt;br&gt;Christoph Volpers, Michalski Hüttermann &amp; Partner, Germany</td>
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<td>17:15-17:45</td>
<td>Dosing, double patenting and the US biosimilars landscape&lt;br&gt;Nabeela Rasheed, McAndrews, Held &amp; Malloy, Ltd, USA</td>
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### Panel Discussion
Day 2  June 28, 2016
Melia Meeting 1+2

Keynote Forum

09:00-09:45  Strategies 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 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 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 Zafar Sadek, Renata Ltd., Bangladesh
Supporting Organizations

Poster Presentations

Panel Discussion

Award Ceremony

Day 3  June 29, 2016

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

Bookmark your dates

6th International Conference and Exhibition on

Biologics and Biosimilars

October 19-21, 2016  Houston, Texas, USA

Web: www.biosimilars-biologics.pharmaceuticalconferences.com