**For Available Speaker Slots**
eurobiosimilars@pharmaceuticalconferences.org

11th European Biosimilars Congress
April 26-27, 2018 | Rome, Italy

Theme: “The developmental strategies and uptake of biosimilars through a decade in Europe”
# Program at a Glance

<table>
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<tr>
<th>Time</th>
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<tr>
<td>08.00-09.00</td>
<td>Reception/Registration</td>
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<tr>
<td>09.00-09.15</td>
<td>Inaugural Address</td>
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<tr>
<td>09.15-09.45</td>
<td>Keynote/Plenary Talk 1</td>
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<td>09.45-10.15</td>
<td>Keynote/Plenary Talk 2</td>
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<td>10.15-10.45</td>
<td>Keynote/Plenary Talk 3</td>
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<th>Time</th>
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<tr>
<td>09.00-10.40</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
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<tr>
<td>10.00-10.40</td>
<td>Coffee/Tea Break 10.40-10.55 (Networking)</td>
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<tr>
<td>10.55-12.35</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
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<tr>
<td>13.25-15.05</td>
<td>5 Speakers (20 Mins Each)</td>
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<td>15.05-15.20</td>
<td>Coffee/Tea Break 15.05-15.20 (Networking)</td>
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<tr>
<td>15.20-17.00</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
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**For More Details, Visit:** [http://biosimilars-biologics.pharmaceuticalconferences.com/europe/](http://biosimilars-biologics.pharmaceuticalconferences.com/europe/)
Conference Highlights:

- Current Challenges in Developing Biosimilars
- Emerging Biosimilars in Therapeutics
- Analytical Strategies for Biosimilars
- Regulatory Approach of Biosimilars
- Legal Issues and BPCI Act
- Innovative Approach for Biosimilars
- Biosimilars Research Pipeline
- Consequences of Brexit on Biosimilars
- Intellectual Property Rights
- Globalization of Biosimilars
- Bioequivalence Assessment
- Clinical Development of Biosimilars
- BCS and IVIVC Based Biowaivers
- Biosimilar Market and Cost Analysis
- Challenges in Biosimilars Pharmacovigilance
- Biosimilar Companies and Market Analysis
- Entrepreneurs Investment Meet

For detailed sessions, please visit: http://biosimilars-biologics.pharmaceuticalconferences.com/europe/
Submit your abstract online at: http://biosimilars-biologics.pharmaceuticalconferences.com/europe/abstract-submission.php
Register online: http://biosimilars-biologics.pharmaceuticalconferences.com/europe/registration.php
11th European Biosimilars Congress
April 26-27, 2018 Rome, Italy

Euro Biosimilars - Past Participated Organisations

[Logos of various organisations]
## 11th European Biosimilars Congress

**April 26-27, 2018 Rome, Italy**

#### Euro Biosimilars - Past Participated Organisations

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<td>Altior</td>
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<td>Ege University</td>
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<td>Ruprecht-Karls-Universität Heidelberg</td>
<td>Gefco</td>
<td>Terumo</td>
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<td>Health Canada</td>
<td>The Menarini Group</td>
<td>Michalski Hüttermann Patentanwälte</td>
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<td>Formycon Global Quality Biosimilars</td>
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<td>Theradiag</td>
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Glimpses of Previous Euro Biosimilars Conference

http://biosimilars-biologics.pharmaceuticalconferences.com/europe/
Best Tourist Destinations in Rome, Italy

Colosseum

Roman Forum

Hotel Tiziano

Leaning Tower of Pisa Italy

Milan Cathedral

Rialto Bridge

http://biosimilars-biologics.pharmaceuticalconferences.com/europe/
**Keynote Forum**

**Introduction**

**Title: The commercial landscape for biosimilars: Planning in an uncertain environment**  
Arthur G. Cook, ZS Associates, USA

**Networking & Refreshment Break**

**Title: Intellectual property and regulatory interplay in biosimilars**  
Christoph Volpers, Michalski Hüttermann & Partner, Germany

**Group Photo**

**Lunch Break**

**Sessions: Innovative Approach for Biosimilars | Clinical Development of Biosimilars | Emerging Biosimilars in Therapeutics**  
**Session Chair: Tim Demuth**

**Title: CMC considerations for biosimilar drug development**  
Ulrike Konrad, Karl Ruprecht Universität, Germany  
**Title: Search for unknown immunogenicity: An overview**  
Rosa Helena Bustos, University of La Sabana, Colombia

**Networking & Refreshment Break**

**Title: Development of Etanercept biosimilar Erelzi™**  
Tim Demuth, Sandoz, Germany  
**Title: Development and in-vivo evaluation of Ofloxacin gastro-retentive drug delivery system**  
Dina E Abo Elezz, Pharos University, Egypt

**Panel Discussion**

**Keynote Forum**

**Introduction**

**Title: How AbbVie tries to fend off world’s blockbuster No 1 from generic competition**  
Ulrich Storz, Michalski Hüttermann & Partner, Germany

**Networking & Refreshment Break**

**Title: Innovative, cost effective solution for self-administration of Bio-similar drugs**  
Tsachi Shaked, E3D Elcam Drug Delivery Devices, Israel  
Menachem Zucker, E3D Elcam Drug Delivery Devices, Israel

**Lunch Break**

**Sessions: Biosimilar Market and Cost Analysis | Analytical Strategies for Biosimilars | Globalization of Biosimilars**  
**Session Chair: Tim Demuth**

**Title: Evidence-based approach of CT-P13 to meet the expectations of different stakeholders**  
Stanley Seung Suh Hong, Celltrion Healthcare Co. Ltd., South Korea
Title: Multilevel characterization of biosimilars by CE-LIF and CE-MS
Andras Guttman, University of Pannonia, USA

Title: Development of a methodology for the evaluation of tumor necrosis factor antibody (anti-TNF-alpha) in patients with treatment of biological products through the use of Nanobiosensors
Efraín Esteban, University of La Sabana, Colombia

Title: Study of liver toxicity and its reversibility of Cassytha filiformis defatted ethanolic extract on mice
Armenia Nazar, University of Andalas, Indonesia

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<td>Poster Presentations</td>
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**EBP 01**
Title: Polymer-based prefillable syringes designed to minimize the aggregation risk of sensitive biodrugs
Katsuyuki Takeuchi, Terumo Corporation, Japan

**EBP 02**
Title: Improved biologics workflow utilizing a single, automated platform to effectively monitor protein stability
Marco Schwieder, NanoTemper Technologies GmbH, Germany

**EBP 03**
Title: Investigation of chemoprevention properties of Halopteris scoparia brown algae by using in vivo bioluminescent imaging
Özgenur Erdokur, Ege University, Turkey

**EBP 04**
Title: Inflectra—our experience on immunogenicity (case series)
Rodica Olteanu, Colentina Clinical Hospital, Romania

**EBP 05**
"Title: Development of a methodology for the evaluation of tumor necrosis factor antibody (anti-TNF-alpha) in patients with treatment of biological products through the use of nanobiosensors
Zapata C, University of La Sabana, Colombia

**EBP 06**
Title: How can modeling and simulation optimize the clinical development of adalimumab biosimilar candidates?
Bernardo Miguel-Lillo, SGS Exprimo, Belgium

**Award Ceremony**
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<td>Introduction</td>
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</table>
| **Title:** Biosimilars: Latin America’s Coming On Board: Regulatory Approval and Market Access  
**Marlene Llópiz-Avilés**, Association of Medical Specialists in the Pharmaceutical Industry, Mexico | |
| **Title:** The Commercial Landscape for Biosimilars: Planning in an Uncertain Environment  
**Arthur G Cook**, ZS Associates, USA | |
| **Title:** Impact of Biosimilars on Patent Portfolio Development and Management  
**Kristin A. Connarn**, McDermott Will & Emery, USA | |
| **Title:** Biosimilars in treatment of multiple sclerosis in Iran  
**Hossein Pakdaman**, Shahid Beheshti University of Medical Sciences, Iran | |
| **Title:** Systematic Shortlisting of Candidate Molecules and Biosimilar/Biobetter Product Development: An Undergraduate Research Effort  
**Balram Pani**, Bhaskaracharya College of Applied Sciences -University of Delhi, India | |
| **Title:** Emerging biosimilars in the USA – quo vadis  
**Melissa Law**, Technology Catalysts International, USA | |

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<td><strong>Keynote Forum</strong></td>
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</table>
| **Title:** Use of Biophysical Techniques for the Analysis of Biosimilars  
**Mario DiPaola**, Blue Stream Laboratories, Inc, USA | |
| **Title:** Scientific Factors in Biosimilar Product Development  
**Laszlo Endrenyi**, University of Toronto, Canada | |
| **Title:** Biosimilars Regulations: Updates from Canada  
**Oxana Iliach**, Quintiles, Canada | |
| **Title:** Brexit and Biosimilars  
**Dipti Gulati**, PJI Biotech, USA | |
| **Title:** Evolution of Structure-Function paradigm in Biopharmaceutics based on Global Regulatory Needs  
**Dinesh Palanivelu**, Biocon Research Centre, Bangalore, India | |
| **Title:** Using IPRs In the Biosimilars Context  
**Laura Burson**, Sheppard, Mullin, Richter & Hampton LLP, USA | |
| **Title:** nSMOL-Development of novel LCMS bioanalytical approach by Fab-selective quantitation of monoclonal antibodies using nano-surface and molecular orientation limited proteolysis  
**Takashi Shimada**, SHIMADZU Corporation, Japan | |

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### Keynote Forum

**Day 1  June 27, 2016**

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<th>Title</th>
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<th>Institution</th>
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<tr>
<td>Interchangeability of biological drug products</td>
<td>Laszlo Endrenyi</td>
<td>University of Toronto, Canada</td>
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<tr>
<td>Evaluating immunogenicity biosimilars</td>
<td>Candida Fratazzi</td>
<td>BBCR Consulting, USA</td>
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<tr>
<td>FDA/EMA Current thinking on totality of evidence for biosimilar approvals</td>
<td>Kamali Chance</td>
<td>Quintiles Inc., USA</td>
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<td>Supporting biosimilar clinical trials in the UK</td>
<td>Sarah Cooper</td>
<td>National Health Service, UK</td>
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<td>The emergence of orphan Biosimilars</td>
<td>Triona Bolger</td>
<td>Navigant Consulting, Inc, UK</td>
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<tr>
<td>The importance of IP protection and SPCs for biologics and biosimilar products</td>
<td>Luder Behrens</td>
<td>Boehmert &amp; Boehmert, Germany</td>
</tr>
<tr>
<td>An update on the legal landscape for biosimilars in the USA</td>
<td>Paul A Calvo</td>
<td>Sterne, Kessler, Goldstein &amp; Fox, USA</td>
</tr>
<tr>
<td>Intellectual Property Issues in global biosimilar programs</td>
<td>Christoph Volpers</td>
<td>Michalski Hüttermann &amp; Partner, Germany</td>
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<tr>
<td>Dosing, double patenting and the US biosimilars landscape</td>
<td>Nabeela Rasheed</td>
<td>McAndrews, Held &amp; Malloy, Ltd, USA</td>
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<thead>
<tr>
<th>Title</th>
<th>Speaker</th>
<th>Institution</th>
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<tr>
<td>Strategies for biosimilars development</td>
<td>Andreu Soldevila</td>
<td>LeanBio Pro, Spain</td>
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<td>Establishing “Finger-print like” biosimilarity – Critical characterization steps for biosimilar assessment.</td>
<td>Fiona M Greer</td>
<td>SGS Life Sciences, Switzerland</td>
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<td>Biosimilar development cost: Role of analytics</td>
<td>Dipit Gulati</td>
<td>PJI Biotech, USA</td>
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<td>Pharmacovigilance in cancer medicine</td>
<td>Luis H Camacho</td>
<td>Center for Oncology and Blood Disorders, Houston, USA</td>
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<td>Process Raman Spectroscopy for in-Line monitoring of mammalian cell cultures in real time</td>
<td>Alexander Pitters</td>
<td>Kaiser Optical Systems, SARL, France</td>
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<td>Analytical assessment of biosimilarity – Considerations in study design</td>
<td>Christina Vessely</td>
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<td>Overcoming the challenges of biosimilar development as a mid-size player</td>
<td>Ruediger Jankowsky</td>
<td>Cinfa Biotech, Germany</td>
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<td>Recommendations from the AAPS LBABFG Biosimilars Action Program Committee for the validation of pharmacokinetic and immunogenicity assays in support of Biosimilar drug development</td>
<td>Aparna Kasinath</td>
<td>Syngene International Limited, India</td>
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<td>Impact on technology integration on better and faster Biosimilars pipeline</td>
<td>Christelle Dagoneau</td>
<td>Catalent Biologics, USA</td>
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<td>Biosimilar Globalization – A silver lining in untested waters</td>
<td>Candida Fratazzi</td>
<td>BBCR Consulting, USA</td>
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<td>From neuronal networks to neuromodulation with biosimilars</td>
<td>Luis Ulloa</td>
<td>Rutgers-New Jersey Medical School, USA</td>
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<tr>
<td>High throughput assays for the determination of the potency and comparability of Biosimilars and innovator products</td>
<td>Michael G Tovey</td>
<td>INSERM, France</td>
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<td>Growth potential of Biosimilar products in Bangladesh</td>
<td>Md. Abu Zafor Sadek</td>
<td>Renata Ltd., Bangladesh</td>
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**4th International Conference and Exhibition on Biologics and Biosimilars**

### Day 1  October 26, 2015

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</table>
| **Patrick Lucy**  
Pfenex Inc., USA  
**Kamali Chance**  
Quintiles, USA |
| **Christopher J Leintz**  
Pfizer Inc., USA  
**Mark A Emalfarb**  
Dyadic International Inc., USA |

Exploring government pricing and reimbursement policy challenges associated with biosimilars  
William A Sarraille, Sidley Austin LLP, USA  
**The economic viability of a U.S. biosimilars industry**  
Alex Brill, Matrix Global Advisors, USA  
**Challenges and approaches in demonstrating biosimilarity at the physicochemical and biological level**  
Jill A Myers, Momenta Pharmaceuticals, USA  
**Clearing the path for market entry before the USPTO**  
Y Jenny Chen, Wolf Greenfield & Sacks, PC, USA  
**Similar biologics in India – legal and regulatory perspective**  
Milind Antani, Nishith Desai Associates, India  
**US biosimilars taking flight: Discussion of the key events and cases shaping the US biosimilar landscape**  
Timothy J Shea, Sterne Kessler Goldstein & Fox PLLC, USA  
**Biosimilars market access and penetration in the Obama care era – considerations for providers, payers, prescribers and patients**  
Gary C Cupit, Somnus Therapeutics, USA  
**U.S. biosimilars – The courts interpret BCPIA steps**  
Denise M Kettelberger, Sunstein Kann Murphy & Timbers LLP, USA  
**AVX-470, an Orally-Delivered GI-Targeted anti-TNF Biobetter**  
Neil L Schauer, Avaxia Biologics, USA  
**Challenges of the recombinant pharmaceutical biosimilar proteins expression and enhanced refolded recovery from E.coli**  
Vivek Kumar Morya, Inha University, Republic of Korea  
**Emerging biosimilar in therapeutics: Where we are and what is future?**  
Dipti Gulati, PJ Biotech, USA

### Day 2  October 27, 2015

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| **Sarfaraz K Niazi**  
Therapeutic Proteins International, USA  
**Angela Furlanetto**  
Dimock Stratton LLP, Canada |

Impact of the biosimilars pipeline and nomenclature on market development  
Ronald A Rader, Biotechnology Information Institute, USA  
**Evolution of the global biosimilars market: Lessons learned**  
Raymond A Huml, Quintiles Inc., USA  
**Biosimilars: Is the risk worth the reward**  
James Harris III, Healthcare Economics LLC, USA  
**Biosimilar Companies and Market Development Worldwide**  
Lisa V Mueller, Michael Best & Friedrich LLP, USA  
**Patent eligibility challenges to biologics under America Invents Act (AIA) and Myriad**  
Raj S Davé, Pillsbury Winthrop Shaw Pittman LLP, USA  
**Cost- Effective clinical trial design to detect immunogenicity and efficacy differences between biosimilar and innovator product.**  
Candida Frataazzi, BBCR Consulting, USA  
**Janssen Biotech V. Celltrion: The balance between the BPCIA and litigation**  
Kerisha A Bowen, Dentons US LLC, USA  
**Issues in the clinical development of the first wave of biosimilars**  
Nigel Rulewski, Quintiles, USA  
**Supplementary protection certificates (SPCs) in Europe – What is the ‘basic patent’ and what is the ‘product’?**  
Tom Carver, Wragge Lawrence Graham & Co, UK  
**CMC consideration for biosimilar drug development and manufacturing process**  
Marcus Mreyen, Protagen Protein Services, Germany  
**Overcome challenges to manufacture of biosimilars through media/feed screening and cell culture process optimization**  
Min Zhang, Fujifilm Diosynth Biotechnologies, U.S.A
Erbilux biosimilar

Alan L Epstein, USC Keck School Of Medicine, USA

Production of biosimilar MAbs in transgenic animals-- Opportunities and challenges

Roman T Drews, LFB, USA

Poster Presentation

Identification and quantification of flavonoids and their glycosides for quality assessment of Terminalia species applying liquid chromatography hyphenated with mass spectrometric techniques

Awantika Singh, Central Drug Research Institute, India

Patients Satisfaction on Antiretroviral Therapy Monitoring Laboratory Services in public Hospitals, Addis Ababa, Ethiopia.

Tedla Mindaye, Addis Ababa University, Ethiopia

Improving injection force of high viscous drugs by a unique, commercially available needle created by using tapered technology

Mitsuru Takahashi, Terumo Medical Corporation, USA

Structural Modification of the Alpha-helical Antimicrobial Brevinin-2 Related Peptide – A Comparison Study of Biosimilars

Siqin Liu, Queen’s University Belfast, UK

Ultra performance liquid chromatography mass spectrometric analysis for rapid quantitation of isoquinoline alkaloids in Thalictrum reniforme

Vikas Bajpai, Central Drug Research Institute, India

Cold active endo-glucanase from Antarctic Yeast, Glaciozyma antarctica Pl12; expression and characterisation

Salimeh Mohammadi, University Kebangsaan Malaysia, Malaysia

Day 3 October 28, 2015

Workshop on A review of the how state regulators are dealing with biosimilars, a case study of the Maryland policy debate and legislation

Gene M Ransom III, University of Maryland and University of Baltimore School of Law, USA

Safety and biosimilarity of lori®EPOCIM compared to Eprex® based on toxicologic, pharmacodynamic and pharmacokinetic studies in the Sprague-Dawley rat

Gordon T Bolger, Nucro-Technics, Canada

Prevention potency of soaps and disinfectants on Vancomycin resistant Enterococcus faecalis infection

Adetunji Olawale, Osun State Polytechnic, Nigeria

Bioanalytical challenges of biosimilar development; making you wish you had a mirror to put in front of the innovator drug

Afshin Safavi, BioAgilitytix, USA

Protein binding drug-drug interaction

Marina Babayeva, Touro College of Pharmacy, USA

The characterisation of biosimilar mAbs using biologically relevant and sensitive ADCC methodologies

Andy Upsall, BioOutsorce, UK

Development of a biosimilar CMC strategy for the identification of critical quality attributes

Samantha Little, Covance Laboratories, UK

Characterization of Glatiramer acetate C-terminal heterogeneity

Mario DiPaola, Bluestream Lab., USA

Closing & Award ceremony
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<td><strong>Nigel Rulewski</strong></td>
<td>Steven Lehrer</td>
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<td>Quintiles Inc., USA</td>
<td>Cipla Ltd., USA</td>
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<td><strong>Mohan Dewan</strong></td>
<td>Heike Schon</td>
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<td>R.K. Dewan &amp; Co., India</td>
<td>LUMIS International GmbH, Germany</td>
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Title: A double blind, phase 1, randomized, parallel-group, single dose, 2 arm, biosimilar study, of a "New Biologic" and "Comparator", intravenously administered to healthy subjects

Krishna Menon, Cellceutix Corporation, USA

Title: Biosimilar regulations in the ASEAN

Shivraj Dasari, SLS Cell Cure Technologies Pvt. Ltd., India

Title: Challenges in demonstrating biosimilarity and interchangeability of biosimilar products

Rodeina Challand, PRA Health Sciences, UK

Title: Comparison of US/EU biosimilar guidelines

Kamal Chace, Quintiles Inc., USA

Title: Challenges and its resolutions in the conduct of biosimilars clinical development

Chirag Shah, Cลานtha Research Ltd., India

Title: Quality attributes of biologic products and standard setting process – USP perspective

Ranjan Chakrabarti, United States Pharmacopeia India Pvt. Ltd., India

Title: Emerging trends and biosimilars regulation in India

R Manavalan, Annamalai University, India

Title: Emerging trends in biosimilars and biologics

Kaiser Jamil, Bhagwan Mahavir Research Centre, India

Title: Potential value of biosimilars—will biosimilars be cost effective compared to the branded equivalents?

Shabana Khan, Ecron Acunova, India

Title: Can excluding pharmaceuticals from patenting will lead to cost effective and quality drugs/biosimilars?

Shilpa Bhilegaonkar, PES’s Rajaram & Tarabai Bandekar College of Pharmacy, India

**Workshop**

Title: BCS: A scientific and regulatory tool in drug development process

Sunita Dahya, Globus College of Pharmacy, India

Title: Bioavailability enhancement techniques for BCS Class II and Class IV drugs

Jithan Venkata Aukunuru, Mother Teresa College of Pharmacy, India

**Symposium**

Title: Biosimilars and their prospective future in the market

Murali Bukkapatnam, TiE, India

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<tr>
<td>Krishna Menon</td>
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<tr>
<td>Cellceutix Corporation, USA</td>
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<tr>
<td>Rodeina Challand</td>
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<td>PRA Health Sciences, UK</td>
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Title: Biological and functional characterization of anti-TNFα biosimilar drugs

Daniel Galbraith, BioOutsource Ltd., UK

Title: Evaluation of immunogenicity in biotherapeutics

Surendra J Chavan, Quantimmune Solutions Pvt. Ltd., India

Title: Commercial opportunities in biosimilars

Steve Lehrer, Cipla Ltd., USA

Title: Plant derived cyclopolypeptides: Targets for drug discovery

Rajiv Dahiyia, Association of Pharmacy Professionals, India

Title: Risk assessment: A pragmatic approach to develop biosimilars

Harish Shandilya, INTAS Biopharmaceuticals Ltd., India

Title: Successful conduct of clinical trials to prove biosimilarity by defining a best fit outsourcing strategy

Heike Schoen, LUMIS International GmbH, Germany

Title: Intas–Merck Millipore: Partnership in biosimilars development strategy for emerging markets

Jennifer Campbell, Merck Millipore, France & Shalini Sharma, Intas Pharmaceuticals Ltd, India

Title: Enzyme engineering: An innovative way to manage the economics of biosimilars- Polyclone case study

Naveen Kulkarni, Polyclone Bioservices Pvt. Ltd., India

Title: Roadmap of stability studies for biosimilar product development

Rashbehari Tunga, Stelis Biopharma, India

Title: Future of next generation biosimilars

Kamlesh Patel, Abbott HealthCare Pvt. Ltd., India
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<th>Title: Clinical development of biosimilars: Overcoming challenges</th>
<th>Charu Manaktala, Quintiles Inc., India</th>
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<tr>
<td>Title: Challenges faced in the development of biosimilars</td>
<td>Hima Bindu Gujjarlamudi, Rajiv Gandhi Institute of Medical Sciences (RIMS), India</td>
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<tr>
<td>Title: Clinical trials of biosimilars in developing nations: obstacles and opportunities</td>
<td>N Srinivas, Malla Reddy Institute of Pharmaceutical Sciences, India</td>
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<tr>
<td>Title: Best practices for high concentration ultrafiltration applications</td>
<td>Subhashis Banerjee, Merck Millipore, India</td>
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<tr>
<td>Title: Bioanalytical strategy for biosimilars: Recommended steps for establishment of comparability</td>
<td>Aparna Kasinath, Cognigen International Ltd., India</td>
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<tr>
<td>Title: Understanding osteomyelitis and its solution through cost effective biomaterial based strategies</td>
<td>Smit Kumar Nand, West Bengal University of Animal and Fishery Sciences, India</td>
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<tr>
<td>Title: Virus filtration for biosimilar manufacturing: from needs to solutions</td>
<td>Tathagata Ray, Merck Millipore, India</td>
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<tr>
<td>Title: An alternate approach for sialic acid estimation in erythropoietin by HPAEC-PAD method</td>
<td>R Jayachandran, United States Pharmacopeia India Pvt. Ltd., India</td>
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<tr>
<td>Title: Analytical biosimilarity: Strategies and challenges</td>
<td>Shalini Sharma, Intas Pharmaceuticals Ltd., India</td>
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<tr>
<td>Title: Alternate approaches addressing variability in ADCC assay</td>
<td>Prabhavathy Munagala, United States Pharmacopeia India Pvt. Ltd., India</td>
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Presentations @ Hall 4

Day 3 October 29, 2014

<table>
<thead>
<tr>
<th>Title: Biosimilars in the United States—Update on FDA implementation and other current issues</th>
<th>James C Shehan, Hyman, Phelps &amp; McNamara, USA</th>
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<tbody>
<tr>
<td>Title: The positive role of intellectual property in the creation of cost effective and affordable biosimilars</td>
<td>Mohan Dewan, R.K. Dewan &amp; Co., India</td>
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<tr>
<td>Title: IP checklist for similar biologics</td>
<td>Mita Sheikh, Krishna &amp; Saurasti Associates, India</td>
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<tr>
<td>Title: Patent issues in biopharmaceutical industry</td>
<td>Vijay Kumar, BioBridge Healthcare Solutions Pvt. Ltd., India</td>
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<tr>
<td>Title: The exclusions from patentability and especially the rationale for medical use patents</td>
<td>Dieter Tzschoppe, European Patent Office, Germany</td>
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</tbody>
</table>

Coffee Break 10:40-10:55 @ Hall 4

<table>
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<tr>
<th>Title: Patenting of biosimilars in India and related issues</th>
<th>Vijay Kumar Makyam, IP Markets, India</th>
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<tr>
<td>Title: Compulsory licensing: A delicate balance between biosimilars and innovations</td>
<td>Poongothai A R, IP Markets, India</td>
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<tr>
<td>Title: Challenges for biosimilar generics</td>
<td>Vivek Kashyap, Lex Orbis IP Practice, India</td>
</tr>
<tr>
<td>Title: Preparing for U.S. market entry—strategy considerations in view of BPCIA and AIA</td>
<td>Renita S Rathinam, Sughrue Mion PLLC, USA</td>
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<tr>
<td>Title: Biosimilars: Globalization of biosimilars</td>
<td>Ravi R Ghnghas, Govt. Medical College, India</td>
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<td>Title: A next generation sequencing approach drives target personalized therapy of acute myeloid leukemia</td>
<td>Giovanni Martinelli, Bologna University School of Medicine, Italy</td>
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<td>Title: Host cell protein and other impurity clearance assays for biosimilar development</td>
<td>Arumugam Muruganandam, Affigenix Biosolutions Pvt. Ltd., India</td>
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<td>Nigel Rulewski, Quintiles Inc., USA</td>
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<td>Title: Pharmacovigilance of biosimilars: Challenges &amp; possible solutions</td>
<td>J Vijay Venkatraman, Oviya MedSafe, India</td>
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<td>Title: Role of pharma industries in the improvement of pharmacovigilance system</td>
<td>Kamlesh Patel, Abbott HealthCare Pvt. Ltd., India</td>
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<td>Title: Synergism of ‘nutraceutical’ and ‘pharmaceutical’ for safety</td>
<td>Ekta K Kalra, Ekta K Kalra Writing Company, India</td>
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<td>Title: The key roles &amp; responsibilities of pharmacists in biosimilars development</td>
<td>N Srinivas, Malla Reddy Institute of Pharmaceutical Sciences, India</td>
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Panel Discussion: 15:40-15:45

Young Researcher Forum

<table>
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<tr>
<th>Title: Bimodal gastroretentive drug delivery systems of lamotrigine: Formulation and evaluation</th>
<th>Rajasekhar Reddy Poonuru, St. Peter’s Institute of Pharmaceutical Sciences, India</th>
</tr>
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<tr>
<td>Title: Dissolution testing of nicotinamide cocrystals of a model BCS Class-II drug</td>
<td>Rajasekhar Reddy Poonuru, St. Peter’s Institute of Pharmaceutical Sciences, India</td>
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Panel Discussion: 15:40-15:45
Title: Medication usage and nutritional status in hemodialysis
S Chan Mubeena, Sri Padmavathi Mahila Viswavidyalayam, India

Title: Combined approach of biosimilar trastuzumab monoclonal antibody with nanoparticles targeted to prostate tumor cells
Dubey Satendra Kumar, JSS University, India

Title: Effect of lipid digestion media on the fate of drug in lipid based nanoemulsion
R Suresh Kumar, JSS University, India

Title: Design and synthesis of some novel antibacterial agents targeting Gyrase B and Par E
Janarthanan T, JSS University, India

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Title: The quest for cost effective treatment in rheumatoid arthritis: Are biosimilars the right choice?
Phani Kishore Thimmarama, Pharmax Market Access Solutions, India

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Title: Posters Presentation @ Hall 4

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Janarthanan T, JSS University, India

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Title: Demonstration of multivariate data analysis for the development of *Boswellia serrata* plant extracts containing nanoemulsion
Mukesh Gohel, Anand Pharmacy College, India

Title: In vivo characterization of snail extract loaded marine biomaterials in bone regeneration
Piyali Das, West Bengal University of Animal and Fishery Sciences, India

Title: Effect of curcumin in celecoxib and streptozotocin induced experimental dementia of Alzheimer disease in mice
Ahsas Goyal, DGLA University, India

Title: Recombinant version of streptokinase: An overview
Alice Jaya Pradha Cheekurthy, Acharya Nagarjuna University, India

Title: Development and evaluation of digestive enzyme formulations
Chaudhari Nilesh B, Sandip Institute of Pharmaceutical Sciences, India

Title: Serotonin storm- A drug induced syndrome
Lilli Sailaja G, Doctor of Pharmacy Association, India

Title: Global perspectives and future implications of biosimilars in next generation treatment
Jemy Rajan, Doctor of Pharmacy Association, India

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Title: Survey of US certified diabetes educators (CDEs) suggests high interest in future use of biosimilar insulin due to cost savings
Jessica Dong, Close Concerns Inc., USA

Title: In vivo characterization of snail extract loaded marine biomaterials in bone regeneration
Piyali Das, West Bengal University of Animal and Fishery Sciences, India

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Title: Flow cytometric analysis of DNA content and expression of natalizumab in the PBMCs of patients with rheumatoid arthritis
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Title: The omega-3 fatty acids serves as alternate safe new pharmacological treatment for cardio vascular diseases which effectively decreases the mortality
M Manasa Rekha, Doctor of Pharmacy Association, India

Title: Investigation of actual chemical constituents and anti-inflammatory activity of Arka leaves extracts
Mohammed Rageeb Mohammed Usman, Smt. Sharadchandrika Suresh Patil College of Pharmacy, India

Title: Antihypertensive effect of leaves of *Tephrosia purpurea* Linn. on isolated frog heart
Sufiyin Ahmad, Gangamai College of Pharmacy, India

Title: Development of validated analytical method for risperidone in pharmaceutical solid dosage form by HPTLC
Sunil Singh, Mewar University, India

Title: Synthesis and pharmacological screening of some benzimidazole derivatives
Sunita T Patil, P.S.G.V.P.M’s College of Pharmacy, India

Title: Acceptance of biosimilar products in the treatment of rheumatoid arthritis
Narendra Kumar Vemulapalli, Doctor of Pharmacy Association, India

Title: Development and validation of RP-HPLC method for simultaneous estimation of cefixime and clavulanic acid from tablet dosage-form
Wankhede Ajit R, Sandip Institute of Pharmaceutical Sciences, India

Title: Risk of stroke in smokers
B Jyothi, Doctor of Pharmacy Association, India

Title: Over the counter drugs - Advantages and risks of self-management of OTC drugs in older adult patients
B Neelima, Doctor of Pharmacy Association, India

Title: Neuroleptic malignant syndrome - A neuroleptic induced syndrome
K V Jagadeesh, Doctor of Pharmacy Association, India

Title: Evaluation of behavioural studies of *Linum usitatissimum*
R Naga Kishore, Geethanjali College of Pharmacy, India

Title: Cefpodoxime proxetil gastretentive effervescent floating tablets by using various hydrophilic polymers
M Naga Ganesh, Geethanjali College of Pharmacy, India
Title: Development and validation of UV- spectrophotometric simultaneous equation method for simvastatin and ezetimibe in tablet formulation
Murtadak Sagar N, Sandip Institute of Pharmaceutical Sciences, India

Title: Bioanalysis of riluzole in human plasma by a sensitive LC-MS/MS method and its application to a pharmacokinetic study in South Indian subjects
Anjaneyulu Narapusetti, Geethanjali College of Pharmacy, India

Title: Pharmaceutical care program educate patient on quality of life (QOL) in type 2 diabetes mellitus in Dhule
Tabrez Mujawar, R. C. Patel Institute of Pharmaceutical Education & Research, India

Title: Extraction and characterization of gum from Lepidium sativum Linn. and Cordia dichotoma Linn. for its film forming properties and studies about release characteristic of these films
Vaibhav M Darvhekar, P. Wadvani College of Pharmacy, India

Title: Biosimilars-destination in India
J Sadhana Reddy, Anurag Group of Institution, India

Title: Liquisolid technique for dissolution enhancement of hormones belonging to BCS Class II
Sameer Nadaf, Bharati Vidyapeeth College of Pharmacy, India

Title: New visible spectrophotometric methods for the assay of spiramycin
Karteek Rao Amperayani, GITAM University, India

Title: Pharmacognostic studies, biamthraquinones and spermidine alkaloid from Cassia floribunda
Podila Venu, The University of Greenwich, UK

Title: Search for effective antimycotic agents against Microsporum gypseum from 61 ethno medicinal plants of Hyderabad Karnataka region, India
Shivakumar Singh P, Gulbarga University, India

Title: Current problems and future aspects of pharmacovigilance in india
Pragnya Devi U, Doctor of Pharmacy Association, India

Title: Synthesis and biological activity of a cyclic hexapeptide from Dianthus superbus
Suresh Beniwal, Kurukshetra University, India

Title: Potential role of pharma-industries in addressing the challenges in pharmacovigilence: Practice changes & outcome trends
Malawika Maheshwari K, Doctor of Pharmacy Association, India

Title: Anti-cancer biosimilars from natural products
P V Lalith, Gurunanak Institute of Pharmacy, India

Title: Assessment of knowledge, adherence and attitude of patients towards tuberculosis, its medications and effect of counselling in a medical college outpatient clinic
Syeda Sumayya Siraj, Deccan School of Pharmacy, India

Title: Cost-effectiveness and pharmacoeconomic analysis of combined inhaled corticosteroids and bronchodilators for severe and very severe COPD patients and health related quality of Life of COPD patients in a teaching hospital
Mohammed Altaf, Deccan School of Pharmacy, India

Title: Synthesis and antimicrobial screening of 1, 2, 4 H-triazole derivatives
Neha Yadav, VNS Faculty of Pharmacy, India

Title: Agrobacterium-mediated genetic transformation of tobacco cells and annexin gene cloning using pTZ57R/T vector
Jithender D, Osmania University, India