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

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

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


<table>
<thead>
<tr>
<th>Time</th>
<th>Session 1</th>
<th>Session 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.00-10.40</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
</tr>
<tr>
<td></td>
<td>Coffee/Tea Break 10.40-10.55 (Networking)</td>
<td></td>
</tr>
<tr>
<td>10.55-12.35</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
</tr>
<tr>
<td></td>
<td>Lunch Break 12.35-13.25</td>
<td></td>
</tr>
<tr>
<td>13.25-15.05</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
</tr>
<tr>
<td></td>
<td>Coffee/Tea Break 15.05-15.20 (Networking)</td>
<td></td>
</tr>
<tr>
<td>15.20-17.00</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
</tr>
</tbody>
</table>

For More Details, Visit: http://biosimilars-biologics.pharmaceuticalconferences.com/europe/
Euro Biosimilars 2018 - 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

http://biosimilars-biologics.pharmaceuticalconferences.com/europe/
11th European Biosimilars Congress
April 26-27, 2018 Rome, Italy

Euro Biosimilars - Past Participated Organisations

http://biosimilars-biologics.pharmaceuticalconferences.com/europe/
Glimpses of Biosimilars Conferences

http://biosimilars-biologics.pharmaceuticalconferences.com/europe/
Scientific Program

Proceedings of

7th European Biosimilars Congress

May 15-16, 2017 Munich, Germany

Conference Series - America
One Commerce Center-1201, Orange St. #600, Wilmington,
Zip 19899, Delaware, USA

Conference Series - UK
Kemp House, 152 City Road, London EC1V 2NX, UK
Toll Free: +1-800-014-8923
Day 1  May 15, 2017

Lilli Palmer

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

Session Introduction

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

Day 2  May 16, 2017

Lilli Palmer

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

Session Introduction

Title: Evidence-based approach of CT-P13 to meet the expectations of different stakeholders
Stanley Seung Suh Hong, Celltrion Healthcare Co. Ltd., South Korea
**Poster Presentations**

| 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-TNFalpha) 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**
<table>
<thead>
<tr>
<th>Day 1</th>
<th>October 19, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conference Series</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Opening Ceremony</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Keynote Forum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Introduction</strong></td>
</tr>
</tbody>
</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 |

<table>
<thead>
<tr>
<th>Day 2</th>
<th>October 20, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Keynote Forum</strong></td>
<td></td>
</tr>
</tbody>
</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  
*László 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 |

<table>
<thead>
<tr>
<th>Day 3</th>
<th>October 21, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Networking Refreshments</strong></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>June 27, 2016</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
</tr>
<tr>
<td>Title: Interchangeability of biological drug products</td>
<td>Laszlo Endrenyi, University of Toronto, Canada</td>
</tr>
<tr>
<td>Title: Evaluating immunogenicity biosimilars</td>
<td>Candida Frataazzi, BBCR Consulting, USA</td>
</tr>
<tr>
<td>Title: FDA/EMA Current thinking on totality of evidence for biosimilar approvals</td>
<td>Kamali Chance, Quintiles Inc., USA</td>
</tr>
<tr>
<td>Title: Supporting biosimilar clinical trials in the UK</td>
<td>Sarah Cooper, National Health Service, UK</td>
</tr>
<tr>
<td>Title: The emergence of orphan Biosimilars</td>
<td>Triona Bolger, Navigant Consulting, Inc, UK</td>
</tr>
<tr>
<td>Title: The importance of IP protection and SPCs for biologics and biosimilar products</td>
<td>Luder Behrens, Boehmert &amp; Boehmert, Germany</td>
</tr>
<tr>
<td>Title: An update on the legal landscape for biosimilars in the USA</td>
<td>Paul A Calvo, Sterne, Kessler, Goldstein &amp; Fox, USA</td>
</tr>
<tr>
<td>Title: Intellectual Property Issues in global biosimilar programs</td>
<td>Christoph Volpers, Michalski Hüttermann &amp; Partner, Germany</td>
</tr>
<tr>
<td>Title: Dosing, double patenting and the US biosimilars landscape</td>
<td>Nabeela Rasheed, McAndrews, Held &amp; Malloy, Ltd, USA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day 2</th>
<th>June 28, 2016</th>
<th>Keynote Forum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title: Startegies for biosimilars development</td>
<td>Andreu Soldevila, LeanBio Pro, Spain</td>
<td></td>
</tr>
<tr>
<td>Establishing “Finger-print like” biosimilarity–Critical characterization steps for biosimilar assessment.</td>
<td>Fiona M Greer, SGS Life Sciences, Switzerland</td>
<td></td>
</tr>
<tr>
<td>Title: Biosimilar development cost: Role of analytics</td>
<td>Dipi Gulati, PJI Biotech, USA</td>
<td></td>
</tr>
<tr>
<td>Title: Pharmacovigilance in cancer medicine</td>
<td>Luis H Camacho, Center for Oncology and Blood Disorders, Houston, USA</td>
<td></td>
</tr>
<tr>
<td>Title: Process Raman Spectroscopy for in-Line monitoring of mammalian cell cultures in real time</td>
<td>Alexander Pitters, Kaiser Optical Systems, SARL, France</td>
<td></td>
</tr>
<tr>
<td>Title: Analytical assessment of biosimilarity – Considerations in study design</td>
<td>Christina Vessely, Biologics Consulting, USA</td>
<td></td>
</tr>
<tr>
<td>Title: Overcoming the challenges of biosimilar development as a mid-size player</td>
<td>Ruediger Jankowsky, Cinfa Biotech, Germany</td>
<td></td>
</tr>
<tr>
<td>Title: 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, Syngene International Limited, India</td>
<td></td>
</tr>
<tr>
<td>Title: Impact on technology integration on better and faster Biosimilars pipeline</td>
<td>Christelle Dagoneau, Catalent Biologics, USA</td>
<td></td>
</tr>
<tr>
<td>Title: Biosimilar Globalization- A silver lining in untested waters</td>
<td>Candida Frataazzi, BBCR Consulting, USA</td>
<td></td>
</tr>
<tr>
<td>Title: From neuronal networks to neuromodulation with biosimilars</td>
<td>Luis Ulloa, Rutgers-New Jersey Medical School, USA</td>
<td></td>
</tr>
<tr>
<td>Title: High throughput assays for the determination of the potency and comparability of Biosimilars and innovator products</td>
<td>Michael G Tovey, INSERM, France</td>
<td></td>
</tr>
<tr>
<td>Title: Growth potential of Biosimilar products in Bangladesh</td>
<td>Md. Abu Zafor Sadek, Renata Ltd., Bangladesh</td>
<td></td>
</tr>
</tbody>
</table>
4th International Conference and Exhibition on Biologics and Biosimilars

Day 1 October 26, 2015

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

Day 2 October 27, 2015

<table>
<thead>
<tr>
<th>Keynote Forum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sarfaraz K Niazi</td>
</tr>
<tr>
<td>Therapeutic Proteins International, USA</td>
</tr>
<tr>
<td>Angela Furlanetto</td>
</tr>
<tr>
<td>Dimock Stratton LLP, Canada</td>
</tr>
</tbody>
</table>

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 Fratazzu, 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, USA |
**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

---

**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 ior®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**

Mariana 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**
### Day 1  October 27, 2014

| Keynote Forum |
|---------------|---------------|
| **Nigel Rulewski** | **Steven Lehrer** |
| Quintiles Inc., USA | Cipla Ltd., USA |
| **Mohan Dewan** | **Heike Schoen** |
| R.K. Dewan & Co., India | LUMIS International GmbH, Germany |

**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

**Kamali Chance,** Quintiles Inc., USA

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

**Chirag Shah,** Cianthra Research Ltd., India

**Title:** Being-similar: From benchside to bedside

**Manish Mahajan,** Lupin Ltd., India

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

**Ranjit 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 Medical 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

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

**Sunita Dahiyia,** 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

**Title:** Biomarkers in clinical trials for drug development

**Harish Patel,** University College London, UK

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

**Jithan Venkata Aukunuru,** Mother Teresa College of Pharmacy, India

**Title:** Understanding the role of bioavailability in drug development

**Sunita Dahiyia,** Globus College of Pharmacy, India

**Title:** Bioanalytical aspects of biosimilar development

**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 Dahiya,** 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 Biopharmaceuticals 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

**Title:** Emerging trends in biosimilars and biologics

**Kaiser Jamil,** Bhagwan Mahavir Medical 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

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

**Sunita Dahiyia,** 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

**Title:** Understanding the role of bioavailability in drug development

**Sunita Dahiyia,** Globus College of Pharmacy, India

**Title:** Bioanalytical aspects of biosimilar development

**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 Dahiya,** 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 Biopharmaceuticals 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

**Title:** Emerging trends in biosimilars and biologics

**Kaiser Jamil,** Bhagwan Mahavir Medical 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

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

**Sunita Dahiyia,** 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

**Title:** Understanding the role of bioavailability in drug development

**Sunita Dahiyia,** Globus College of Pharmacy, India

**Title:** Bioanalytical aspects of biosimilar development

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

**Day 3 October 29, 2014**

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

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

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

Panel Discussion: 15:40-15:45

**Young Researcher Forum**

Title: Bimodal gastroretentive drug delivery systems of lamotrigine: Formulation and evaluation
Rajasekhar Reddy Poonuru, St. Peter's Institute of Pharmaceutical Sciences, India
Title: Dissolution testing of nicotinamide cocrystals of a model BCS Class-II drug
Kale Mohana Raghava Srivalli, IIT (BHU), India
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 antibiotic agents targeting Gyrase B and Par E
Janarthanan T, JSS University, 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 antibiotic agents targeting Gyrase B and Par E
Janarthanan T, JSS University, India

---

Title: The quest for cost effective treatment in rheumatoid arthritis: Are biosimilars the right choice?
Phani Kishore Thimmaraaju, Phamax Market Access Solutions, 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: 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: 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 type2 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, bianthraquinones and spermidine alkaloid from Cassia floribunda
Podila Venu, The University of Greenwich, UK

Title: Search for effective antymycotic 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
Malwika 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