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Tentative Program

# 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**


**Conference Series**

Kemp House, 152 City Road

London EC1V 2NX, UK

Toll Free: +1-800-014-8923

Email: eurobiosimilars@conferenceseries.net

# 11th European Biosimilars Congress

## April 26-27, 2018 | Rome, Italy

### Program at a Glance

#### Day 1

| | | |
|---|---|---|
| **Reception/Registration** | **08.00-09.00** | |
| | **Time** | **General Session** |
| Morning Sessions | 09.00-09.15 | Inaugural Address |
| Least of 3 Keynote/Plenary Talks | 09.15-09.45 | Keynote/Plenary Talk 1 |
| | 09.45-10.15 | Keynote/Plenary Talk 2 |
| | 10.15-10.45 | Keynote/Plenary Talk 3 |
| Panel Discussions/Group Photo | | |
| **Coffee/Tea Break 10.45-11.00 (Networking)** | | |
| 11.00-12.40 | 5 Speakers (20 Mins Each) | |
| | | |
| **Lunch Break 12.40-13.30** | | |
| Evening Sessions 13.30-15.30 | 6 Speakers (20 Mins Each) | |
| | | |
| **Coffee/Tea Break 15.30-15.45 (Networking)** | | |
| 15.45-17.25 | 5 Speakers (20 Mins Each) | |

19 Speakers for **Day 1**

#### Day 2

| | | | |
|---|---|---|---|
| | **Time** | **Session 1** | **Session 2** |
| Morning Sessions 09.00-10.40 | | 5 Speakers (20 Mins Each) | 5 Speakers (20 Mins Each) |
| **Coffee/Tea Break 10.40-10.55 (Networking)** | | | |
| 10.55-12.35 | | 5 Speakers (20 Mins Each) | 5 Speakers (20 Mins Each) |
| | | | |
| **Lunch Break 12.35-13.25** | | | |
| **Evening Sessions 13.25-15.05** | | **5 Speakers (20 Mins Each)** | **5 Speakers (20 Mins Each)** |
| Poster Sessions | | | |
| **Coffee/Tea Break 15.05-15.20 (Networking)** | | | |
| **15.20-17.00** | | **5 Speakers (20 Mins Each)** | **5 Speakers (20 Mins Each)** |

40 Speakers on **Day 2**

**For More Details,** Visit : http://biosimilars-biologics.pharmaceuticalconferences.com/europe/

## Collaborations

BSTP

European Nanoscience and Nanotechnology Association

Swiss Biotech Association ACADEMY

# OCM - Euro Biosimilars 2018



**Robert Salcedo**
USA



**Kamali Chance**
USA



**Francois-Xavier Frapaise**
France



**Fiona M Greer**
Switzerland



**Nelly Adel**
USA



**Dipti Gulati**
USA



**Andras Guttman**
Hungary



**Christoph Volpers**
Germany

# Media Partners

































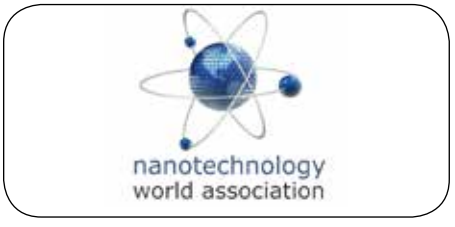





















# Conference Highlights:

- *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

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# 11th European Biosimilars Congress

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

## Euro Biosimilars - Past Participated Organisations




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

# 11th European Biosimilars Congress

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

## Euro Biosimilars - Past Participated Organisations

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# *Glimpses of Previous Euro Biosimilars Conference*


















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

# Best Tourist Destinations in Rome, Italy



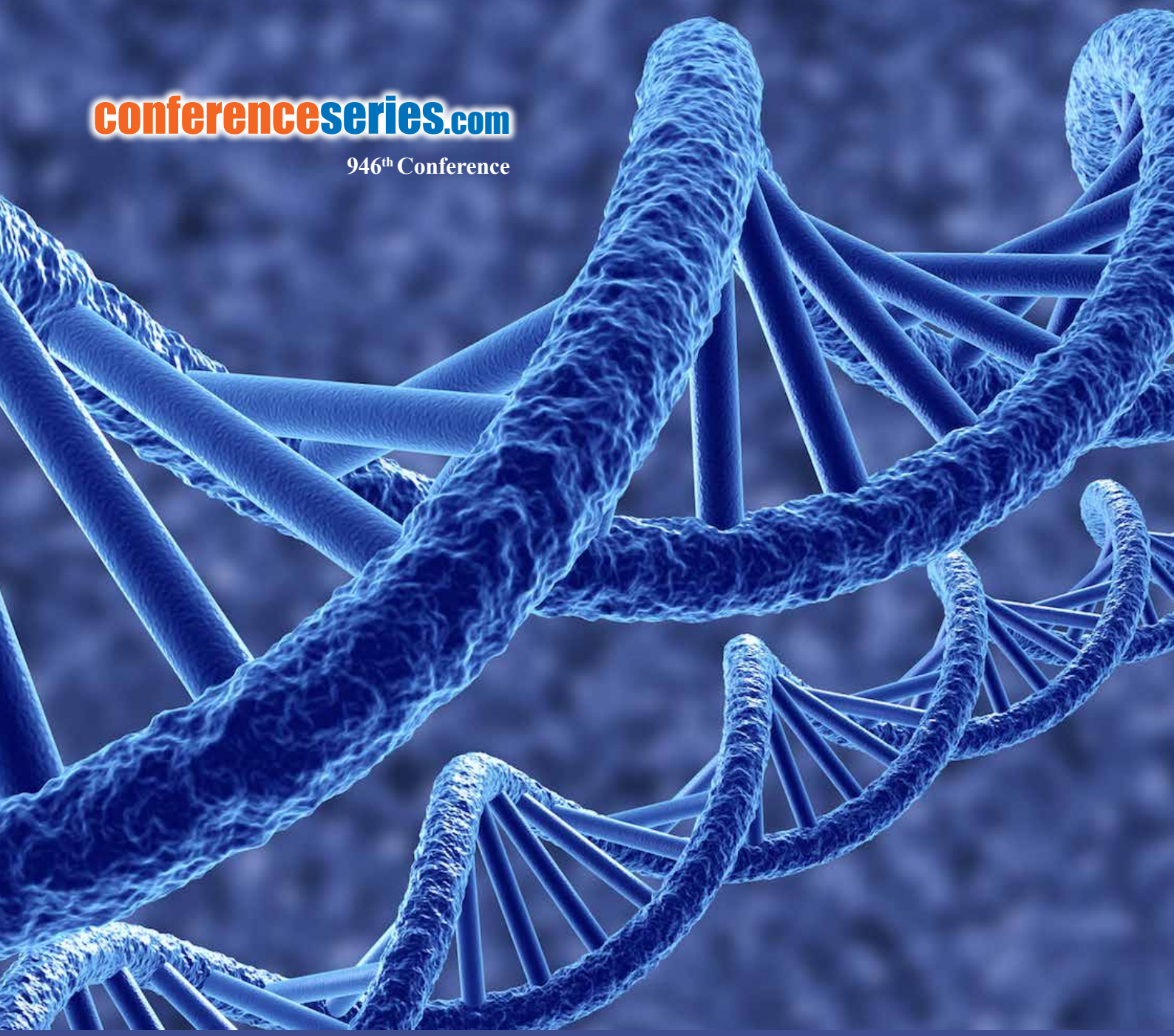












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Proceedings of

# 7th European Biosimilars Congress

May 15-16, 2017 Munich, Germany


**Conference Series - America**

One Commerce Center-1201, Orange St. #600, Wilmington,
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**Conference Series - UK**

Kemp House, 152 City Road, London EC1V 2NX, UK
Toll Free: +1-800-014-8923

## Day 1 May 15, 2017

Registrations

Lilli Palmer

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# Opening Ceremony

## 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

**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

| | |
|---|---|
| | **Networking & Refreshment Break** |
| | **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** |



## Day 1 October 19, 2016

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# Opening Ceremony

## Keynote Forum

**Introduction**

**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

## Day 2 October 20, 2016

## Keynote Forum

**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

## Day 3 October 21, 2016

## Networking Refreshments

# 5TH EUROPEAN BIOSIMILARS CONGRESS

## Day 1 June 27, 2016

### Keynote Forum

**Title: Interchangeability of biological drug products**
**Laszlo Endrenyi,** University of Toronto, Canada

**Title: Evaluating immunogenicity biosimilars**
**Candida Fratazzi,** BBCR Consulting, USA

**Title: FDA/EMA Current thinking on totality of evidence for biosimilar approvals**
**Kamali Chance,** Quintiles Inc., USA

**Title: Supporting biosimilar clinical trials in the UK**
**Sarah Cooper,** National Health Service , UK

**Title: The emergence of orphan Biosimilars**
**Triona Bolger,** Navigant Consulting, Inc, UK

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

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

**Title: Intellectual Property Issues in global biosimilar programs**
**Christoph Volpers,** Michalski Hüttermann & Partner, Germany

**Title: Dosing, double patenting and the US biosimilars landscape**
**Nabeela Rasheed,** McAndrews, Held & Malloy, Ltd, USA

## Day 2 June 28, 2016

### Keynote Forum

**Title: Startegies for biosimilars development**
**Andreu Soldevila,** LeanBio Pro, Spain

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

**Title: Biosimilar development cost: Role of analytics**
**Dipti Gulati,** PJI Biotech, USA

**Title: Pharmacovigilance in cancer medicine**
**Luis H Camacho,** Center for Oncology and Blood Disorders, Houston, USA

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

**Title: Analytical assessment of biosimilarity – Considerations in study design**
**Christina Vessely,** Biologics Consulting, USA

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

**Title: 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

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

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

**Title: From neuronal networks to neuromodulation with biosimilars**
**Luis Ulloa,** Rutgers-New Jersey Medical School, USA

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

**Title: Growth potential of Biosimilar products in Bangladesh**
**Md. Abu Zafor Sadek,** Renata Ltd., Bangladesh

## Day 1 October 26, 2015

### Keynote Forum

**Patrick Lucy**
Pfenex Inc., USA

**Christopher J Leintz**
Pfizer Inc., USA

**Kamali Chance**
Quintiles, 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,** PJI Biotech, USA

## Day 2 October 27, 2015

### Keynote Forum

**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 Fratazzi,** 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

**Erbitux 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-helicalAntimicrobial 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 Thalictrumreniforme**
**Vikas Bajpai,** Central Drug Research Institute, India
**Cold active endo-glucanase from Antarctic Yeast, Glaciozyma antarctica PI12; 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 biosimlairs. 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,** BioAgilytix, 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**
Quintiles Inc., USA

**Mohan Dewan**
R.K. Dewan & Co., India

**Steven Lehrer**
Cipla Ltd., USA

**Heike Schon**
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,** Cliantha 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**
**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 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

### Workshop

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

## Day 2 October 28, 2014

### Keynote Forum

**Krishna Menon**
Cellceutix Corporation, USA

**Rodeina Challand**
PRA Health Sciences, UK

**Title: Biological and functional characterization of anti-TNFα biosimilar durgs**
**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 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 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

**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,** Clinigene 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

**` Presentations @ Hall 4**

## 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: IP 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 Makyam,** 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**
**Arumugam 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 antibacterial agents targeting Gyrase B and Par E**
**Janarthanan T,** JSS University, India

## Posters Presentation @ Hall 4

**Title: The quest for cost effective treatment in rheumatoid arthritis: Are biosimilars the right choice?**
**Phani Kishore Thimmaraju,** 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: Recombinant version of streptokinase: An overview**
**Alice Jaya Pradha Cheekurthy,** Acharya Nagarjuna University, India
**Title: Demonstration of multivariate data analysis for the development of *Boswellia serratta* plant extracts containing nanoemulsion**
**Mukesh Gohel,** Anand Pharmacy College, 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

**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: Drug release kinetics in polymeric delivery systems**
**M Vani,** Doctor of Pharmacy Association, India
**Title: The challenge of tuberculosis to the global public health care: A clinical pharmacist perspective**
**Khadeer Ahmed Ghori,** Doctor of Pharmacy Association, India
**Title: The Indian pharmaceutical industries should support dichloroacetate (DCA): A new potential metabolic-targeting drug available at low price for cancer treatment**
**M Manasa Rekha,** Doctor of Pharmacy Association, India
**Title: The omega-3 fatty acids serves as alternate safe new pharmacological treatment for cardio vascular diseases which effectively decreases the mortality**
**M Navya Sree,** 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: Drug discovery: Though chemi-bioinformatics-from system to market**
**M Murali Mohan Gutti,** JNTU, India
**Title: Monitoring adverse drug reaction of various pharmaceutical products in rural population of South India**
**Stefin Mary Mathew,** Doctor of Pharmacy Association, India
**Title: Antihypertensive effect of leaves of *Tephrosia purpurea* Linn. on isolated frog heart**
**Sufiyan 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**
**Sunila 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 cloxacillin 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 gastroretentive 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 type2 diabetes mellitus in Dhule**
**Tabrej 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 spectrophometric methods for the assay of spiramycine**
**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 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 Maheswari 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 brochodilators 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