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Tentative Program

# 7th European Biosimilars Congress

**May 15-16, 2017 Munich, Germany**

*Theme: "The developmental strategies and uptake of Biosimilars through a decade in Europe"*



## **For Available Speaker Slots**

**eurobiosimilars@conferencesmail.org**


**Conference Series**

57 Ullswater Avenue, West End, Southampton, Hampshire
United Kingdom, SO18 3QS
Toll Free: +1-800-216-6499
Email: eurobiosimilars@pharmaceuticalconferences.org

# 7th European Biosimilars Congress

**May 15-16, 2017 Munich, Germany**

## Program at a Glance

### Day 1

| | | |
|---|---|---|
| **Reception/Registration** | **08.00-09.00** | |
| | **Time** | **General Session** |
| Least of 3 Keynote/Plenary Talks | 09.00-09.15 | Inaugural Address |
| | 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** | | |
| 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) | |

Morning Sessions / Evening Sessions

19 Speakers for **Day 1**

### Day 2

| | | | |
|---|---|---|---|
| | **Time** | **Session 1** | **Session 2** |
| 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** | | | |
| **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)** |

Morning Sessions / Evening Sessions

40 Speakers on **Day 2**

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

**FEATURED PRESENTATIONS**

## Tentative Scientific Program

Speaker opportunities available, submit your abstract online @
http://biosimilars-biologics.pharmaceuticalconferences.com/europe/call-for-abstracts.php

## SPEAKERS

**Christoph Volpers**, Michalski Hüttermann & Partner, Germany
**Title :** Intellectual Property and Regulatory Interplay in Biosimilars

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

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

**Ulrike Konrad**, Karl Ruprecht Universität, Germany
**Title :** CMC Considerations for Biosimilar Drug Development

**Arthur G. Cook**, ZS Associates, USA
**Title :** The Commercial Landscape for Biosimilars: Planning in an Uncertain Environment

**Tim Demuth**, Sandoz, Germany
**Title :** Development of etanercept biosimilar Erelzi

**Andras Guttman**, University of Pannonia, USA
**Title :** Multilevel characterization of biosimilars by CE-LIF and CE-MS

**Rosa Bustos RH,** Universidad de La Sabana, Colombia
**Title :** Search for unknown immunogenicity: An overview

**Dina E Abo Elezz**, Pharos University, Egypt
**Title :** Development and *in-vivo* evaluation of ofloxacin gastro-retentive drug delivery system

**NOTE: Program is subject to change with final allotment of the speaker slots**

| |
|---|
| **Özgenur Dokur**, Ege University Turkey<br>**Title :** Investigation of chemoprevention properties of *Halopteris scoparia* brown algae by using *in vivo* bioluminescent imaging |
| **Rodica Olteanu**, Colentina Clinical Hospital, Romania<br>**Title :** Inflectra-our experience on immunogenicity (case series) |
| **Efraín Esteban**, University of La Sabana, Colombia<br>**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 nano biosensors |
| **Ravish Patel**, EPR Centre for Cancer Research & Bioinformatics Pvt. Ltd., India<br>**Title :** Physicochemical and functional characterization of a bio-similar Bevacizumab |
| **Christian B Fulda**, Jones Day, Germany<br>**Title :** Consequences of Brexit on biosimilars |
| **Kamali Chance**, QuintilesIMS, USA<br>**Title :** FDA/EMA current thinking on totality of evidence for development of biosimilars |
| **Armenia Nazar**, University of Andalas, Indonesia<br>**Title** : Study of liver toxicity and its reversibility of *Cassytha filiformis* defatted ethanolic extract on mice |
| **Asif Mahmood**, Pfizer, United States<br>**Title :** Biosimilars: Challenges in safety and risk management |
| **M A Attia**, Assiut University, Egypt<br>**Title :** Hydrophobic ion-pairing of low molecular weight heparin with cationic amphiphiles |

**NOTE: Program is subject to change with final allotment of the speaker slots**

# 7th European Biosimilars Congress

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## Media Partners & Exhibitors

# 7th European Biosimilars Congress

**May 15-16, 2017 Munich, Germany**

## Top Participating Organisations




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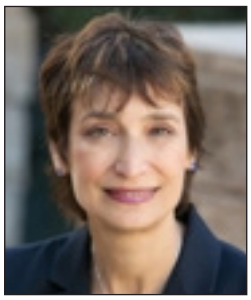
# Previous Speakers



Patrick Lucy
Pfenex Inc. , USA



Alex Brill
Matrix Global Advisors , USA



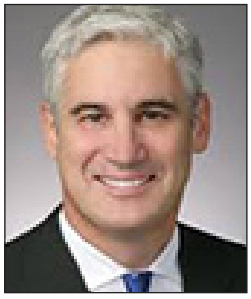
Jill A. Myers
Momenta Pharmaceuticals, USA



Jenny Chen
Wolf, Greenfield & Sacks, P.C , USA



Milind Antani
Nishith Desai Associates, India



William A. Sarraille
Sidley Austin LLP
USA



Timothy J Shea
Sterne, Kessler, Goldstein & Fox P.L.L.C , USA



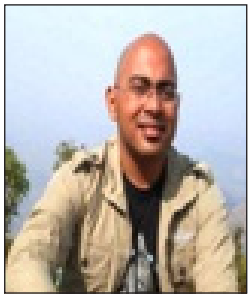
Denise M Kettelberger
Sunstein Kann Murphy & Timbers LLP, USA



Gregory J Glover
Pharmaceutical Law Group PC, USA



Christopher J Leintz
Pfizer, Inc, USA



Subir Roy
DGM- Marketing & Medical at Zydus Cadila, India



Sunit Maity
Theramyt Novobiologics Pvt. Ltd., India



Mark A. Emalfarb
Dyadic International, Inc.
USA



Vivek Kumar Morya
Inha University, Republic of Korea.
South Korea

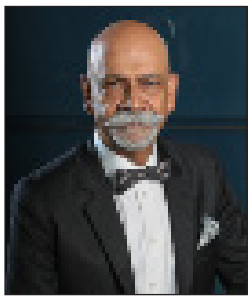


Abdel Halim Harrath
King Saud University
Saudi Arabia



Neil Schauer
Avaxia Biologics
USA

# Previous Speakers



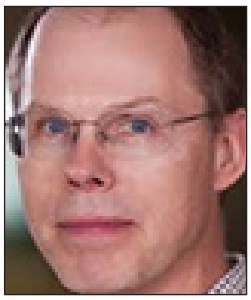
Sarfaraz K. Niazi
TheraProteins, USA



Angela Furlanetto
Dimock Stratton LLP
Canada



Ronald A Rader
Biotechnology
Information Institute, USA



Raymond A Huml
Quintiles, Inc., USA



James Harris III
Healthcare
Economics LLC, USA



Lisa Mueller
Michael Best &
Friedrich LLP, USA



Raj Dave
Pillsbury Winthrop Shaw
Pittman, LLP, USA



Kerisha A. Bowen
Dentons US LLC, USA



Abe Hershkovitz
Hershkovitz &
Associates, PLLC, USA



Nigel J Rulewski
Quintiles, Inc., USA



András Guttman
University of
Pannonia,Hungary SCIEX, USA



Sumant Chaubey
Bills Biotech, India



Andreu Soldevila
CEO LeanBioPro
Spain



Tom Carver
Wragge Lawrence
Graham & Co, UK



Christoph Volpers
Senior Patent Consultant
at Michalski &
Hüttermann, Germany



Wolfgang A. Rehmann
Taylor Wessing
Germany

# Previous Speakers



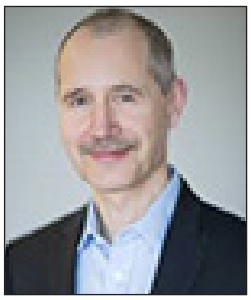
Marcus Mreyen
Protagen Protein Services GmbH, Germany



Min Zhang
Fujifilm Diosynth Biotechnologies USA



Fiona M Greer
SGS Life Sciences Switzerland



Volker Schellenberger
Amunix Operating Inc. USA



Alan L. Epstein
USC Keck School of Medicine, USA



Upendra Nagaich
Amity Institute of Pharmacy, India



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



Gordon T. Bolger
Nucro-Technics Canada



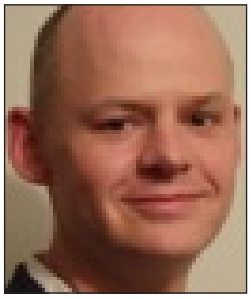
Adetunji Olawale
Osun State Polytechnic Nigeria



Afshin Safavi
BioAgilytix, USA



Mariana Babayeva
Touro College Of Pharmacy USA



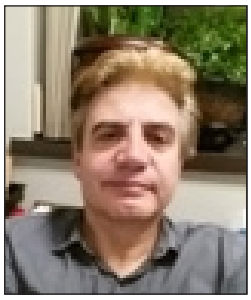
Andy Upsall
BioOutsource, UK



Samantha Little
Covance Laboratories Ltd, UK



Kamali Chance
Quintiles Inc., USA



Mario DiPaola
Blue Stream Laboratories, Inc., USA



Francesco Marchesi
Regina Elena National Cancer Institute, Italy

# Previous Speakers




Candida Fratazzi
BBCR Consulting, USA



Krishna Menon
Cellceutix
Corporation, USA



Daniel Galbraith
BioOutsource Ltd, UK



Siddhartha Roy
CSIR - Indian Institute of
Chemical Biology, India



Noelle Sunstrom
Neuclone PTY LTD
Australia



Dipti Gulati
PJI Biotech, USA



Alexander Pitters
Kaiser Optical Systems
France



Laszlo Endrenyi
University of Toronto
Canada



Christina Vessely
Biologics Consulting, USA



Ruideger Janwosky
Cinfa Biotech GmbH
Germany



Christelle Dagoneau
Catalent Biologics
USA



Aparna Kasinath
Syngene International
India

# *Glimpses of Biosimilars Conferences*




















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## 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