

Oct 27-29, 2014	TENTATIVE SCIENTIFIC PROGRAM				
Eminent Speakers					
					
Nigel Rulewski	Krishna Menon	Harish Pant	Rodeina Challand	CM Gupta	Daniel Galbraith
					
Jennifer Campbell	Heike Schon	Kaiser Jamil	Mohan Dewan	Steven Lehrer	R Chakraborti
26-Oct-14					
	Registrations				
Day 1: 27-10-2014					
08:00-09:00	Registrations				
09:00-09:25	Opening Ceremony				
09:25-09:30	Introduction				
Keynote Forum					
09:30-09:55	Nigel Rulewski, Quintiles Inc., USA				
09:55-10:20	Mohan Dewan, R.K. Dewan & Co., India				
10:20-10:45	Steven Lehrer, Cipla Limited, USA				
10:45-11:10	Heike Schoen, LUMIS International, Germany				
Coffee Break: 11:10-11:30					
11:30-12:30	Workshop				
	BCS: A scientific and regulatory tool in drug development process				
	Dr. Sunita Dahiya, Globus College of Pharmacy, India				
	Nanotechnological advances in the solubility enhancement of BCS Class 2 drugs				
	Dr. Muralidhar Rao Akkaladevi, Maheshwara Institute of Pharmacy, India				
Track 1: Challenges and Regulatory Approach for Biosimilars					
Session Introduction					
12:30-12:50	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, Cellceptix Corporation, USA				
12:50-13:10	Title: Biosimilar regulations in The ASEAN				
	Shivraj Dasari, SLS Cell Cure Technologies Private Limited, India				

13:10-13:30	Title: Challenges in demonstrating biosimilarity and interchangeability of biosimilar products
	Rodeina Challand, PRA Health Sciences, UK
Lunch: 13:30-14:15	
14:15-14:35	Title: Comparison of US/EU biosimilar guidelines
	Kamali Chance, Quintiles Inc., USA
14:35-14:55	Title: Challenges and its resolutions in the conduct of biosimilars clinical development
	Chirag Shah, Cliantha Research Limited, India
14:55-15:15	Title: Being-similar: From benchside to bedside
	Manish Mahajan, Lupin Limited, India
15:15-15:35	Title: Quality attributes of biologic products and standard setting process – USP perspective
	Ranjan Chakrabarti, United States Pharmacopeia, India
15:35-15:55	Title: Emerging trends and biosimilars regulation in India
	R Manavalan, Annamalai University, India
15:55-16:15	Title: Emerging trends in biosimilars and biologics
	Kaiser Jamil, Bhagwan Mahavir Medical Research Centre, India
16:15-16:35	Title: Potential value of biosimilars- Will biosimilars be cost effective compared to the
	Shabana Khan, Ecron Acunova, India
16:35-16:55	Title: Can excluding pharmaceuticals from patenting will lead to cost effective and quality drugs / biosimilars ?
	Shilpa Bhilegaonkar, PES Rajaram & Tarabai Bandekar College of Pharmacy, India
Coffee Break: 16:55-17:10	
Symposium	
17:10-18:10	Title: Biosimilars and their prospective future in the market
	Murali Bukkapatnam, TiE, India

Day 2 28-10-2014	
Keynote Forum	
09:00-09:25	Krishna Menon, Cellceutix Corporation, USA
09:25-09:50	Rodeina Challand, PRA Health Sciences, UK
Track 2: Emerging Biosimilars in Therapeutics	
Session Introduction	
09:50-10:10	Title: Biological and functional characterization of anti-TNFα biosimilar durgs
	Daniel Galbraith, BioOutsource Ltd., UK
10:10-10:30	Title: Evaluation of immunogenicity in biotherapeutics
	Surendra J Chavan, Quantimmune Solutions Pvt. Ltd, India
Coffee Break: 10:30-10:45	
10:45-11:05	Title: Commercial opportunities in biosimilars
	Steven Lehrer, Cipla Limited, USA
11:05-11:25	Title: Plant derived cyclopolypeptides: Targets for drug discovery
	Rajiv Dahiya, Globus College of Pharmacy, India
11:25-11:45	Title: Risk assessment: A pragmatic approach to develop biosimilars
	Harish Shandilya, INTAS Biopharmaceuticals Ltd, India
11:45-12:05	Title: Alternate approaches addressing variability in ADCC assay
	Prabhavathy Munagala, United States Pharmacopeia, India
Track 3: Clinical Studies and Clinicians Prospects for Biosimilars	
Session Introduction	
12:05-12:25	Title: Successful conduct of clinical trials to prove biosimilarity by defining a best fit outsourcing strategy
	Heike Schoen, LUMIS International GmbH, Germany

12:25-12:55	Title: Intas – Merck Millipore: Partnership in biosimilars development strategy for emerging markets
	Jennifer Campbell, Merck Millipore, France & Shalini Sharma, Intas Pharmaceuticals Ltd, India
12:55-13:15	Title: Roadmap of stability studies for biosimilar product development
	Rashbehari Tunga, Stelis Biopharma, India
Lunch Break: 13:15-14:00	
14:00-14:20	Title: Future of next generation biosimilars
	Kamlesh Patel, Abbott HealthCare Pvt. Ltd, India
14:20-14:40	Title: Clinical development of biosimilars: Overcoming challenges
	Charu Manaktala, Quintiles Inc., India
14:40-15:00	Title: Challenges faced in the development of biosimilars
	Hima Bindu Gujjarlamudi, Rajiv Gandhi Institute of Medical Sciences (RIMS), India
15:00-15:20	Title: Clinical Trials of Biosimilars in Developing Nations: Obstacles and Opportunities
	N. Srinivas, Malla Reddy Institute of Pharmaceutical Sciences, India
Track 6: Analytical Strategies	
Track 7: Bioequivalence Assessment	
Track 8: BCS & IVIVC Based Biowaivers	
Session Introduction	
15:20-15:40	Title: Best practices for high concentration ultrafiltration applications
	Subhasis Banerjee, Merck Millipore, India
15:40-16:00	Title: Bioanalytical strategy for biosimilars: Recommended steps for establishment of
	Aparna Kasinath, Clinigene International Limited, India
Coffee Break: 16:00-16:15	
16:15-16:35	Title: Understanding osteomyelitis and its solution through cost effective biomaterial based
	Samit Kumar Nandi, West Bengal University of Animal and Fishery Sciences, India
16:35-16:55	Title: Virus Filtration for Biosimilar Manufacturing: From needs to Solutions
	Tathagata Ray, Merck Millipore, India
16:55-17:15	Title: An alternate approach for sialic acid estimation in erythropoietin by HPAEC-PAD method
	R. Jayachandran, United States Pharmacopeia, India
17:15-17:35	Title: Analytical biosimilarity: Strategies and challenges
	Shalini Sharma, Intas Pharmaceuticals Ltd, India
10:45-12:00	Poster Presentations
14:00-15:00	Poster Presentations

Day 3 29-10-2014

Track 9: Intellectual Property Rights

Session Introduction

09:00-09:20	Title: Biosimilars in the United States – Update on FDA implementation and other current issues
	James C Shehan, Hyman, Phelps & McNamara, USA
09:20-09:40	Title: The positive role of intellectual property in the creation of cost effective and affordable biosimilars
	Mohan Dewan, R.K. Dewan & Co., India
09:40-10:00	Title: Preparing for U.S. market entry – Strategy considerations in view of BPCIA and AIA
	Renita Rathinam, Sughrue Mion PLLC, USA

10:00-10:20	Title: Patent issues in biopharmaceutical industry
	Ganesh Kumraj , BioBridge Healthcare Solutions Pvt. Ltd, India
10:20-10:40	Title: Patentability of Pharmaceuticals in the EPO
	Dieter Tzschoppe , European Patent Office, Germany
Coffee Break: 10:40-10:55	
10:55-11:15	Title: Patenting of biosimilars in India and related issues
	Vijay Kumar Makyam , India
11:15-11:35	Title: Compulsory licensing : A delicate balance between biosimilars and innovations
	Poongothai Ramaswamy , IP Markets, India
11:35-11:55	Title: Challenges for biosimilar generics
	Vivek Kashyap , Lex Orbis IP Practice, India
11:55-12:15	Title: IP checklist for similar biologics
	Mita Sheikh , Krishna & Saurastri Associates, India
Track 4: Globalization of Biosimilars	
Track 5: Biosimilars Innovator Pharmaceutical Products	
Track 10: Pharmacovigilance and its Challenges	
Track 11: Plant Produced Biosimilar Products	
12:15-12:35	Title: Enzyme engineering: An innovative way to manage the economics of biosimilars- Polyclone case study
	Naveen Kulkarni , Polyclone Bioservices Private Limited, India
12:35-12:55	Title: Biosimilars–Globalization of biosimilars
	Ravi R Ghanghas , Govt. Medical College, India
12:55-13:15	Title: A next generation sequencing approach drives target personalized therapy of acute myeloid leukemia
	Giovanni Martinelli , Bologna University School of Medicine, Italy
Lunch Break: 13:15-14:00	
14:00-14:20	Title: Host Cell Protein and Other Impurity Clearance assays for Biosimilar Development
	Arumugam Muruganandam , Affigenix Biosolutions Private Limited, India
14:20-14:40	Title: Safety concerns related to global biosimilars drug development
	Nigel Rulewski , Quintiles Inc., USA
14:40-15:00	Title: Pharmacovigilance of biosimilars: Challenges & possible solutions
	J Vijay Venkatraman , Oviya MedSafe, India
15:00-15:20	Title: Role of pharma industries in the improvement of pharmacovigilance system
	Kamlesh Patel , Abbott HealthCare Pvt. Ltd., India
15:20-15:40	Title: Synergism of 'nutraceutical' and 'pharmaceutical' for safety
	Ekta K Kalra , Ekta K Kalra Writing Company, India
15:40-16:00	Title: The key roles & responsibilities of pharmacists in biosimilars development
	N. Srinivas , Malla Reddy Institute of Pharmaceutical Sciences, India
Coffee Break: 16:00-16:15	
Young Researcher Forum	
16:20-16:40	Title: Bimodal gastroretentive drug delivery systems of lamotrigine: Formulation and evaluation
	Rajasekhar Poonuru , St. Peter's Institute of Pharmaceutical Sciences, India
16:40-16:50	Title: Dissolution testing of nicotinamide cocrystals of a model BCS-class-II drug
	Kale Mohana Raghava Srivalli , IIT (BHU), India
16:50-17:00	Title: Medication usage and nutritional status in hemodialysis
	S. Chan Mubeena , Sri Padmavathi Mahila Viswavidyalayam, India
17:00-17:10	Title: Combined approach of biosimilar trastuzumab monoclonal antibody with nanoparticles targeted to prostate tumor cells
	Dubey Satendra Kumar , JSS University, India

17:10-17:20	Title: Effect of lipid digestion media on the fate of drug in lipid based nanoemulsion
	R. Suresh Kumar, JSS University, India
17:20-17:30	Title: Design and Synthesis of Some Novel Antibacterial Agents Targeting Gyrase B and Par E
	Janarthanan.T, JSS University, India
17:30-17:40	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
Award Ceremony	

Please note that this is a tentative program. Timings in this program may subject to change

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