Thursday, 15th November

08:30-09:00  Registrations

09:00-09:30  Introduction

09:30-09:50  COFFEE BREAK

09:50-11:50  MEETING HALL 01
             MEETING HALL 02
             Talks On: Generic drugs, generic pills and generic medication
             Talks On: Protein biotherapeutics and biosimilars
             Biosimilar and biologics
             Developing biosimilars and biobetters
             Pharmacovigilance and safety of biosimilars
             Biosimilar development challenges
             Biosimilars uptake and patient safety
             Pharmacology and drug development
             Generics and biosimilars industry strategy
             Case study mitigating risk in biosimilar development

11:50-13:10  Talks On: Pharma pricing and market access
             Talks On: Licensing, manufacturing and health economics
             Generic Market and Business Opportunities
             Lifecycle management of drug products
             Analysis of key therapeutic areas and leading generic drugs
             Patents and disputes case studies
             Market forecasts are provided for sub markets and their subcategories
             INDA Rules and Regulations
             Array of clinical trials in biosimilars
             Cost-minimization analysis
             Patent access and intellectual property and FDA regulations
             Quality control and R&D

13:10-13:15  GROUP PHOTO

13:15-14:00  LUNCH BREAK

14:00-16:00  MEETING HALL 01
             MEETING HALL 02
             Talks On: Pharma pricing and market access
             Talks On: Licensing, manufacturing and health economics
             Generic Market and Business Opportunities
             Lifecycle management of drug products
             Analysis of key therapeutic areas and leading generic drugs
             Patents and disputes case studies
             Market forecasts are provided for submarkets and their subcategories
             INDA Rules and Regulations
             Array of clinical trials in biosimilars
             Cost-minimization analysis
             Patent access and intellectual property and FDA regulations
             Quality control and R&D

16:00-16:20  COFFEE BREAK

16:00-17:00  Young Researchers in Pharmaceutical Sciences 2019

16:20-18:00  Workshop

https://generic-market.pharmaceuticalconferences.com/
09:00-10:30  
Meeting Hall 01

KEYNOTE LECTURES

10:30-10:50  
COFFEE BREAK

10:50-12:50  
MEETING HALL 01  
Talks On:  
Office of generic drugs (OGD)  
OGD and OPQ review  
OPQ update  
OGD update  
New Product Development  
Patent innovations

MEETING HALL 02  
Talks On:  
Biosimilars differentiated through novel drug delivery technologies  
Product Similarity for Biosimilars & Analytical Challenges  
Role of Medical Affairs in Biosimilars  
Regulatory strategy for generics and biosimilars  
Related Conference of Biosimilars differentiate  
Preclinical and Clinical Development  
Optimising biosimilar clinical trial design

12:50-13:35  
LUNCH BREAK

13:35-15:55  
MEETING HALL 01  
Talks On:  
Innovation and technology for biosimilar development  
Biosimilar Product Reimbursement and Pricing  
Biosimilar Regulatory Updates and Legal Implications  
Biosimilar Market Access and Commercialization  
Case studies of biosimilar approvals/rejections  
Challenges in clinical development

MEETING HALL 02  
Talks On:  
Global generic trends and global pharma market  
Pharmacokinetic and pharmacodynamics properties of generic drugs  
Implementation of TRIPS in developing countries  
Trends for investing in biopharma manufacturing  
Market size forecasts for generic drug  
Generic Market and Business Opportunities

15:55-16:15  
COFFEE BREAK

Poster Presentations  
Workshop

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Special Session on
Comparison of Stelara biosimilar with originator using a PK ELISA

Arkadiusz Wyrzucki
Senior Scientist
Celerion, Switzerland

Keynote Speech on
The End of Phase 3 Clinical Trials in Biosimilars Development

Francois-Xavier Frapaise
Principal
FX Frapaise Consulting, France

Collaborators

https://generic-market.pharmaceuticalconferences.com/
Organizing Committee
Generic Biosimilars 2018

Emmanuel O. Akala
Professor
Howard University
USA

Kurt R. Karst
Director
Hyman, Phelps & McNamara
USA

Anka G. Ehrhardt
Director
Bristol-Myers Squibb Co
USA

Christoph Volpers
Senior Patent Consultant
Michalski Hüttermann & Partners,
Germany

Anna Szemik-Hojniak
Director
INWES Education and Research Institute
USA

Adam Le Gresley
Professor
Kingston University
United Kingdom

Igor Klepikov
Professor
Tel Aviv University
USA

Andrea Nicolini
Professor
University of Pisa
Italy

Kamali Chance
Chief Regulatory Officer
BioSciencesCorp
USA

Dieter Heber
Professor
University of Kiel
Germany

Pillhun Son
Projects Coordination Manager
American Chemical Society
USA

Christopher Tirotta
Director
Nicklaus Children’s Hospital
USA

Dipti Gulati
President
PJI Biotech
USA

George Perry
Dean
University of Texas
USA

Sophia Zi Gu
Professor
University of New South Wales
Australia

George Schroeder
Executive Director
American Academy of Urgent Care Medicine
USA

Pierre A. Morgon
CEO
MRGN Advisors, Geneva
Switzerland

Zeeshan Ahmad
Professor
De Montfort University
United Kingdom

Adnan Sabir
Principal Consultant & Founder
Pharma Consulting Services
USA
Previous Speakers

Raymond A Huml
Quintiles, USA

Nigel J Rulewski
Quintiles, Inc, USA

James Harris
Healthcare Economics LLC, USA

Ronald A Rader
Biotechnology Information Institute, USA

András Guttman
University of Pannonia, Hungary
SCIEX, USA

Sumant Chaubey
Bills Biotech, India

Tom Carver
Wragge Lawrence Graham & Co, UK

Andreu Soldevila
CEO LeanBioPro, Spain

Sarfaraz K. Niazi
TheraProteins, USA

Christoph Volpers
Senior Patent Consultant at Michalski & Hüttermann, Germany

Wolfgang A. Rehmann
Taylor Wessing, Germany

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

Angela Furlanetto
Dimock Stratton LLP, Canada

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Previous Speakers

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, USA

Francesco Marchesi
Regina Elena National Cancer Institute, Italy

Candida Fratazzi
BBCR Consulting, USA

Krishna Menon
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

Michael G Tovey
INSERM, France

Christina Vessely
Biologics Consulting, USA

Ruideger Janwosky
Cinfa Biotech GmbH, Germany

Christelle Dagoneau
Catalent Biologics, USA

Aparna Kasinath
Syngene International, India

Denise M Kettelberger
Sunstein Kann Murphy & Timbers LLP

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Berlin Attractions

- Berlin cathedral
- Brandenburg Gate
- Berlin Victory Column
- Reichstag Building
- Staatsoper Berlin
- Frensehtrum
- Dahlem Botanical Garden
- Museumsinsel
- Bode Museum
Important Dates

Abstract submission opens: April 01, 2018
Registration opens: April 01, 2018
On spot registration: November 15, 2018

Contact Us

Missy Christen | Program Director
Generic Biosimilars 2018
47 Churchfield Road, London, W3 6AY

W: https://generic-market.pharmaceuticalconferences.com/
E: genericpharma@pharmaceuticalconferences.org
Toll Free: +1-702-508-5200 Ext. 8028