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14th International Conference on

Generic Drugs and Biosimilars

November 15-16, 2018
Berlin, Germany



SCIENTIFIC PROGRAM

DAY 1
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 **KEYNOTE LECTURES**

11:50-13:10

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 developement
Generics and biosimilars industry strategy	Case study mitigating risk in biosimilar development

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 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

16:00-16:20 COFFEE BREAK

MEETING HALL 01 (16:20-17:00)	MEETING HALL 01 (17:00-18:00)
Young Researchers in Pharmaceutical Sciences 2019	Workshop

DAY 2
Friday, 16th November

09:00-10:30 Meeting Hall 01 — **KEYNOTE LECTURES**

10:30-10:50 COFFEE BREAK

10:50-12:50

MEETING HALL 01	MEETING HALL 02
Talks On: Office of generic drugs (OGD)	**Talks On:** Biosimilars differentiated through novel drug delivery technologies
OGD and OPQ review	Product Similarity for Biosimilars & Analytical Challenges
OPQ update	Role of Medical Affairs in Biosimilars
OGD update	Regulatory strategy for generics and biosimilars
New Product Development	Related Conference of Biosimilars differentiate
Patent innovations	Preclinical and Clinical Development
	Optimising biosimilar clinical trial design

12:50-13:35 LUNCH BREAK

13:35-15:55

MEETING HALL 01	MEETING HALL 02
Talks On: Innovation and technology for biosimilar development	**Talks On:** Global generic trends and global pharma market
Biosimilar Product Reimbursement and Pricing	Pharmacokinetic and pharmacodynamics properties of generic drugs
Biosimilar Regulatory Updates and Legal Implications	Implementation of TRIPS in developing countries
Biosimilar Market Access and Commercialization	Trends for investing in biopharma manufacturing
Case studies of biosimilar approvals/ rejections	Market size forecasts for generic drug
Challenges in clinical development	Generic Market and Business Opportunities

15:55-16:15 COFFEE BREAK

MEETING HALL 01 (16:15-17:00)	MEETING HALL 01 (17:00-18:00)
Poster Presentations	Workshop

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

Organizing Committee
Generic Biosimilars 2018



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Howard University
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Professor
De Montfort University
United Kingdom



Adnan Sabir
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Pharma Consulting Services
USA

Previous Speakers



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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



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Wragge Lawrence Graham & Co
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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

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



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Krishna Menon
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Glimpses of Generic Biosimilars Conferences

















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Berlin Attractions

















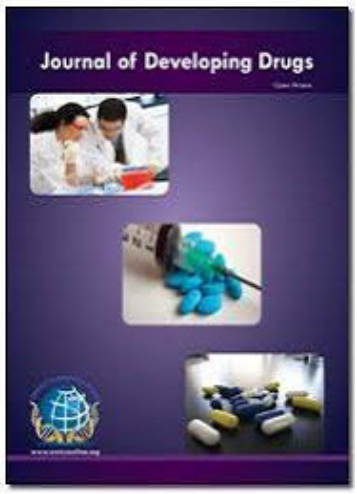


Generic Biosimilars 2018

- Drug Designing: Open Access
- Journal of Bioequivalence & Bioavailability
- Journal of Developing Drugs







Important Dates

Abstract submission opens: **April 01, 2018**

Registration opens: **April 01, 2018**

On spot registration: **November 15, 2018**

Venue & Accommodation

Berlin, Germany

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