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# 14<sup>th</sup> International Conference on **Generic Drugs and Biosimilars**

**November 15-16, 2018  
Frankfurt, Germany**

**S C I E N T I F I C   P R O G R A M**

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
<b>Talks On: Generic drugs, generic pills and generic medication</b>	<b>Talks On: Protein biotherapeutics and biosimilars</b>
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

**13:10-13:15 GROUP PHOTO**

**13:15-14:00 LUNCH BREAK**

14:00-16:00

MEETING HALL 01	MEETING HALL 02
<b>Talks On: Pharma pricing and market access</b>	<b>Talks On: Licensing, manufacturing and health economics</b>
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)
<b>Young Researchers in Pharmaceutical Sciences 2019</b>	<b>Workshop</b>

09:00-10:30  
Meeting Hall 01

**KEYNOTE LECTURES**

**10:30-10:50 COFFEE BREAK**

	MEETING HALL 01	MEETING HALL 02
10:50-12:50	<p><b>Talks On:</b> Office of generic drugs (OGD)</p> <p>OGD and OPQ review</p> <p>OPQ update</p> <p>OGD update</p> <p>New Product Development</p> <p>Patent innovations</p>	<p><b>Talks On:</b> Biosimilars differentiated through novel drug delivery technologies</p> <p>Product Similarity for Biosimilars &amp; Analytical Challenges</p> <p>Role of Medical Affairs in Biosimilars</p> <p>Regulatory strategy for generics and biosimilars</p> <p>Related Conference of Biosimilars differentiate</p> <p>Preclinical and Clinical Development</p> <p>Optimising biosimilar clinical trial design</p>

**12:50-13:35 LUNCH BREAK**

	MEETING HALL 01	MEETING HALL 02
13:35-15:55	<p><b>Talks On:</b> Innovation and technology for biosimilar development</p> <p>Biosimilar Product Reimbursement and Pricing</p> <p>Biosimilar Regulatory Updates and Legal Implications</p> <p>Biosimilar Market Access and Commercialization</p> <p>Case studies of biosimilar approvals/rejections</p> <p>Challenges in clinical development</p>	<p><b>Talks On:</b> Global generic trends and global pharma market</p> <p>Pharmacokinetic and pharmacodynamics properties of generic drugs</p> <p>Implementation of TRIPS in developing countries</p> <p>Trends for investing in biopharma manufacturing</p> <p>Market size forecasts for generic drug</p> <p>Generic Market and Business Opportunities</p>

**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

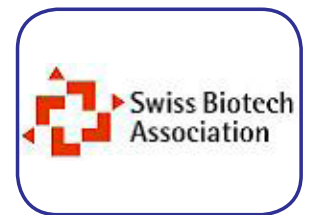
The End of Phase 3 Clinical Trials in Biosimilars Development



**Francois-Xavier Frapaise**

Principal  
FX Frapaise Consulting, France

## Collaborators



# Organizing Committee Generic Biosimilars 2018



**Emmanuel O. Akala**

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Howard University  
USA



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**Christoph Volpers**

Senior Patent Consultant  
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**Pierre A. Morgon**

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**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  
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**András Guttman**  
University of Pannonia, Hungary  
SCIEX, USA



**Sumant Chaubey**  
Bills Biotech, India



**Tom Carver**  
Wragge Lawrence Graham & Co  
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CEO LeanBioPro, Spain



**Sarfaraz K. Niazi**  
TheraProteins, USA



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Senior Patent Consultant at  
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University of Baltimore School of  
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**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 Babayeve**  
Touro College Of Pharmacy, USA



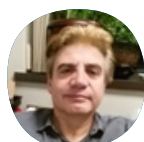
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**Kamali Chance**  
Quintiles Inc., USA



**Mario DiPaola**  
Blue Stream Laboratories, USA



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**Aparna Kasinath**  
Syngene International , India



**Denise M Kettelberger**  
Sunstein Kann Murphy & Timbers  
LLP

# Glimpses of Generic Biosimilars Conferences





# Frankfurt Attractions



Eltz Castle



Heidelberg Tour



Atra Cave



Sightseeing Cruise



Frankfurt City Card



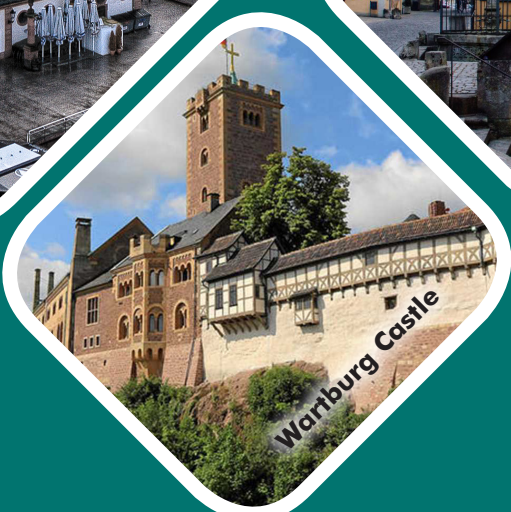
Frankfurt Cathedral



Nuremberg & Rothenburg



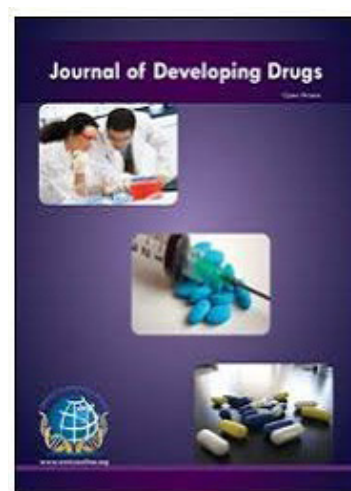
Rhine valley



Wartburg Castle

# 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

Frankfurt, Germany

## Contact Us

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