Program

8th Asian Biologics and Biosimilars Congress
August 10-12, 2017  Beijing, China

Seating is Limited
Register Today!

Conference Secretariat
2360 Corporate Circle, Suite 400 Henderson
NV 89074-7722, USA

Direct: (702) 508-5200 Ext: 8083
Tel: +1 (800) 216 6499
Email: biosimilarsasia@pharmaceuticalconferences.org

http://biosimilars-biologics.pharmaceuticalconferences.com/asiapacific/
Dear Colleagues, Scientists and Friends,

The Organizing Committee is delighted to invite you to attend the 8th Asian Biosimilars Congress, one of its remarkable pharmaceutical conferences, to be held during August 10-12, 2017 in Beijing, China. The Asian Biosimilars Congress 2017 brings together scientists, researchers, industry and CRO representatives from around the world.

As of December 2016 there were 23 biosimilars marketed in the EU and 4 biosimilars licensed in the USA. As such, the biosimilars market is expected to experience an exponential growth over the coming few years. Many new biologics are making their entry in the pharma market and experiencing a notable rise in their usage compared with the conventional medications.

The 8th Asian Biosimilars Congress will present multiple aspects of biosimilars from the passage of biosimilars through a decade in Asia to the latest developments in the field of biologics and biosimilars. The whole range of portfolio selection, development, regulatory requirements and marketing will be presented.

You can join your peers from around the world focused on learning about biologics and biosimilars-related advances, which is your single best opportunity to reach the largest assembly of participants from the Biosimilars community, conduct demonstrations, distribute information, meet with professionals, make a splash with new research, and receive name recognition at this 3-day event.

The congress will provide enough space for discussion, meetings and workshops in order to allow a close contact between speakers and visitors.

We are looking forward to see you in Beijing, China

Raymond Huml, MS, DVM, RAC, QuintilesIMS
Oxana Iliach, PhD, QuintilesIMS
Charu Manaktala, MD, QuintilesIMS
Dear Industry Colleagues, Scientists and Friends,

As a member of the Organizing Committee I am delighted to invite you to attend the 8th Asian Biologics and Biosimilars Congress to be held from August 10-12, 2017 in Beijing, China. The Asian Biosimilars Congress 2017 brings together biopharmaceutical industry colleagues, scientists, researchers, regulatory, and clinical experts from around the globe to bring to you the cutting edge information for the development of biosimilars.

The 8th Asian Biologics and Biosimilars Congress is designed to bring forth the most up to date information for the development of biosimilars. Key aspects will include regulatory, CMC, clinical and marketing considerations, as they relate to what it will take to bring these lifesaving/life altering products to the highly regulated Western Markets.

Please join your peers from around the world for this wonderful opportunity to reach the largest assembly of participants from the Biologics/Biosimilars community, meet with thought leadership experts, share your new research, and show off your cutting edge technology at this 3-day event.

I look forward to seeing you in Beijing, China at the 8th Asian Biologics and Biosimilars Congress.

Kamali Chance
MPH, PhD, RAC
Vice President
Head, Global Biosimilars Regulatory Strategy
Biosimilars Center of Excellence
QuintilesIMS
Focused on immunogenicity and pharmacokinetics

AffinityImmuno

is focused on biosimilars and biological immunogenicity and pharmacokinetics testing. We offer custom and off-the-shelf research and development solutions.

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Asian Biosimilars 2017

Keynote Speakers @ Asian Biosimilars 2017

Kamali Chance
Vice President, Head, Global Biosimilars Regulatory Strategy
Quintiles, Inc., USA

Raymond Huml
Vice President, Quintiles IMS
USA

Oxana Iliach
Sr. Director, Quintiles IMS
Canada

Jianguo Yang
President / CEO, Alpro China Division
USA

Charu Manaktala
Senior Medical Director
Quintiles IMS
India

Hossein Pakdaman
President of Iranian Neurological Association
Iran

Special Session on

Biosimilars: Challenges in Safety and Risk Management

Asif Mahmood
Disease Area Cluster Lead for Biosimilars Pfizer, USA

Asian Biosimilars 2017

http://biosimilars-biologics.pharmaceuticalconferences.com/asiapacific/
Conference Highlights

- Latest Biosimilars in Asian Scenario
- Biosimilars- Hatch-Waxman Act & BPCI Act
- Challenges in Developing Biosimilars
- Biosimilars Research Pipeline
- Current Developments in The Field of Biosimilars
- Pharmacovigilance of Biosimilars
- Emerging Trends in Biosimilars
- Biosimilars Market- Challenges & Prospects
- Cost Analysis of Biosimilars
- Globalization of Biosimilars
- Biosimilars Analytical Strategies
- Emerging Biosimilars in Therapeutics
- Clinical Studies on Biosimilars
- BCS & IVIVC Based Biowaivers
- Entrepreneurs Investment Meet

** Speaker Slots are Available **
Organizing Committee Members

Kamali Chance
Vice President
Quintiles, Inc.
USA

Oxana Iliach
Sr. Director
Quintiles IMS
Canada

Raymond Huml
Vice President
Quintiles IMS
USA

Hossein Pakdaman
Shahid Beheshti University of Medical Sciences
Tehran, Iran

Candida Fratazzi
President
BBCR Consulting
USA

Charu Manaktala
Senior Medical Director
Quintiles IMS
India

Asif Mahmood
Disease Area Cluster
Lead for Biosimilars Pfizer
USA

Suzette DiMascio
CEO & President
CSI Specialty Group
USA

T. Santha Raju
Sr. Director & Head
MedImmune
USA

Lutz Hilbrich
Head of Biosimilars
Platform in China Shanghai,
China

Osama O. Ibrahim
Consultant Biotechnology/
Food Safety
Bioinnovation, USA

Jianguo Yang
President / CEO Abpro
China Division
USA

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Top Participating Organisations

Pfizer
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Celltrion
Novartis
Sandoz
LeanBioPro
Nano Temper Technologies
Patheon
Polpharma
Université Paris Descartes
Catalent Biologics
Protagen Protein Services
Sciex
Servier
SGS
Avaxia Biologics
Cinfab Biotech
University of Birmingham
Universidad de La Sabana
Vitane
TPi
Asphalion
Rīgas Stradiņa Universitāte
Ratiopharm
Tentative Program

Keynote Forums

Title: FDA/EMA Current Thinking on Totality of Evidence for Development of Biosimilars
Kamali Chance, Vice President, Head, Global Biosimilars Regulatory Strategy, Biosimilars Center of Excellence, Quintiles, Inc., USA

Title: Biosimilars: Accelerating Early Clinical Development
Raymond Huml, Vice President, Quintiles IMS, USA

Title: Strategy for the Global Development of Biosimilars: putting it’s all together
Oxana Iliach, Sr. Director, Quintiles IMS, Canada

Title: Strategic Partnership for China Biologics
Jianguo Yang, President / CEO, Abpro China Division, USA

Title: Clinical Development of Biosimilars for Western Markets: Planning for Success
Charu Manaktala, Senior Medical Director, Quintiles IMS, India

Title: Biosimilars in treatment of multiple sclerosis in Iran
Hossein Pakdaman, President of Iranian Neurological Association, Iran

Special Sessions

Title: Biosimilars: Challenges in Safety and Risk Management
Asif Mahmood, Disease Area Cluster lead for Biosimilars, Pfizer, USA

Scientific Sessions

Title: Update on biosimilars litigation in the U.S.: What if you don’t want to dance?
George C. Yu, J.D., M.S., Schiff Hardin LLP, USA

Title: Challenges in Assessing Therapeutic Equivalence of Nano-Similars
Beat Flühmann, Director Vifor Pharma Ltd, Switzerland

Title: Biosimilar Globalization- A silver lining in untested waters! Biosimilars in China: balance of risks and opportunities.
Candida Fratazzi MD, President, BBCR Consulting, USA

Title: The role of regulatory policies in relation to the local biosimilars production
Gustavo H. Marin, PhD, UNLP-CONICET, Argentina

Title: Practical Considerations in Clinical Strategy to Support the Development of Biologics Device Combination Products
Zhaoyang Li, Director, Sanofi, USA

Title: Current status in the development of Biosimilar Market in LATAM region: An update on market barriers, opportunities and regulatory requirements
Edgar Mauricio Rubio Rubio, Pharmacist- Business Development Manager- Biopas- Latam region, USA

Title: From Neuromodulation to Drug Discovery and Treatment
Luis Ulloa, Professor of Surgery at New Jersey Medical School at Rutgers, the state University of New Jersey

Title: Theodor Bilharz Research Institute Therapeutic products and health tools
Ismaei Mohamed, Professor, Ministry of Higher Education and Scientific Research, Egypt

Title: Expression of with Shiga like toxin (SLT) fused to vascular endothelial growth factor (VEGF) in E coli for targeting angiogenesis
Osama O. Ibrahim Ph.D., Consultant Biotechnology, Bio Innovation LLC, USA

Title: Medicines distributions and financing alternatives
Abdeen M Omer, PhD, Khartoum, Sudan
Title: Some Considerations about Biosimilar Safety
Samer M. Al-Hulu, PhD, Al-Qasim Green University, Iraq

Title: The study of Antimicrobial and anti-Alzheimer’s effects of turmeric extract based on amyloid nano-bio-fibrils formation inhibition method
Amir Arasteh, Assistant Professor of Biochemistry, Department of biology, Rasht Branch, Islamic Azad University, Rasht, Iran

Title: Evaluation The Cytotoxicity Of An Oscillatoria Sp. Extract On Breast Cancer Cell Line (Mcf-7) And Assessment Of Noxa Gene Expression
Ali Salehzadeh, Department of Biology, Rasht Branch, Islamic Azad University, Rasht, Iran

Title: Evaluation The Cytotoxicity Of An Oscillatoria Sp. Extract On Breast Cancer Cell Line (Mcf-7) And Assessment Of Noxa Gene Expression
Ali Salehzadeh, Department of Biology, Rasht Branch, Islamic Azad University, Rasht, Iran

Title: Evaluation The Cytotoxicity Of An Oscillatoria Sp. Extract On Breast Cancer Cell Line (Mcf-7) And Assessment Of Noxa Gene Expression
Ali Salehzadeh, Department of Biology, Rasht Branch, Islamic Azad University, Rasht, Iran

Title: Global Status of Biosimilars & Prospects in Asia
Md Abu Zafor Sadek, Institute of Business Administration, University of Dhaka, Bangladesh

Title: Bioassay-Directed Isolation Of Hypotensive Alkaloids From Holarrena Pubescens
Afshar Khalid, H.E.J. Research Institute of Chemistry, University of Karachi, Pakistan

Title: Heterogeneity of Monoclonal Antibody and Challenges in Developing Biosimilar of it
Sunit Maity, PhD, Zumutor, India

Speaker Slots Available
NOTE: Program is subject to change with final allotment of the speaker slots
Previous Speakers

Patrick Lucy
Pfenex Inc
USA

Alex Brill
American Enterprise Institute
USA

Jill Myers
Fortress Biotech
USA

Yahua (Jenny) Chen
Wolf, Greenfield & Sacks, P.C.,
USA

Milind Antani
Nishith Desai Associates
India

William Sarraille
Sidley Austin LLP
USA

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

Denise Kettelberger
Patterson Thuente Pedersen, P.A.,
USA

Gregory Glover
Principal at Pharmaceutical Law
Group PC, USA

Chris Leintz
Pfizer
USA

Subir Roy
Novartis
India

Sunit Maity
Zumutor Biologics
India

Mark Emalfarb
Dyadic International, Inc.,
USA

Vivek morya
Centre for policy research
India

Abdel Halim Harrath
King Saud University
Saudi Arabia

Neil Schauer
Schauer Biologics Consulting, LLC,
USA
Previous Speakers

Sarfaraz K. Niazi
Adello Biologics, LLC
USA

Angela Furlanetto
DLA Piper (Canada) LLP
Canada

Ronald A Rader
Biotechnology Information Institute,
USA

Raymond A Huml
QuintilesIMS
USA

James Harris
Healthcare Economics LLC
USA

Lisa Mueller
Women In Bio
USA

Raj Dave
Pillsbury Winthrop Shaw Pittman LLP, USA

Kerisha Bowen
Dentons US LLC
USA

Abe Hershkovitz
Hershkovitz & Associates, PLLC
USA

Nigel Rulewski
Quintiles
USA

András Guttman
University of Pannonia
Hungary SCIEX, USA

Sumant Chaubey
Bills Biotech
India

Andreu Soldevila
CEO LeanBioPro
Spain

Tom Carver
J A Kemp - Patent and Trade Mark Attorneys, UK

Christoph Volpers
Senior Patent Consultant at Michalski & Hüettermann, Germany

Wolfgang Rehmann
Taylor Wessing
Germany

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Previous Speakers

Marcus Mreyen  
Protagen Protein Services, GmbH, Germany

Min Zhang  
AstraZeneca, USA

Fiona M Greer  
SGS Life Sciences, United Kingdom

Volker Schellenberger  
Amunix Operating Inc., USA

Alan L. Epstein  
USC Keck School of Medicine, USA

Upendra Nagaich  
Amity Institute of Pharmacy, India

Gene Ransom  
CEO MedChi, The Maryland State Medical Society, USA

Gordon Bolger  
Nucro-Technics Inc., Canada

Adetunji Olawale  
Osun State Polytechnic, Nigeria

Afshin Safavi  
BioAgilityx Labs, USA

Mariana Babayeva  
Touro College of Pharmacy, USA

Andy Upsall  
Antibody Analytics, United Kingdom

Samantha (Little) Howard  
Covance Clinical Research Unit, Inc., United Kingdom

Kamali Chance  
Quintiles, IMS, USA

Mario DiPaola  
Blue Stream Laboratories, Inc, USA

Francesco Marchesi  
Regina Elena National Cancer Institute, Italy
Previous Speakers

Candida Fratazzi  
BBCR Consulting  
USA

Noelle Sunstrom  
NeuClone Pty Ltd  
Australia

Christina Vessely  
Biologics Consulting  
USA

Krishna Menon  
Cellicutix  
USA

Dipti Gulati  
PJI Biotech  
USA

Ruediger Jankowsky  
Cinfa Biotech GmbH  
Germany

Siddhartha Roy  
Bose Institute  
India

Daniel Galbraith  
BioSource Ltd  
United Kingdom

Alexander Pitters  
Kaiser Optical Systems  
France

Christelle Dagoneau  
Catalent Biologics  
USA

Laszlo Endrenyi  
University of Toronto  
Canada

Siddhartha Roy  
Bose Institute  
India

Dipti Gulati  
PJI Biotech  
USA

Ruediger Jankowsky  
Cinfa Biotech GmbH  
Germany

Christelle Dagoneau  
Catalent Biologics  
USA

Aparna Kasinath  
Syngene International  
India
**Why to Attend??**

Join your peers around the world focused on learning about Biologics and Biosimilars related advances, which is your single best opportunity to reach the largest assemblage of participants from the Biosimilars community, conduct demonstrations, distribute information, meet with current and potential professionals, make a splash with a new research works, and receive name recognition at this 3-day event. World-renowned speakers, the most recent research, advances, and the newest updates in Biologics and Biosimilars are hallmarks of this conference.

At Asian Biosimilars 2017 meet your target audiences from around the world focused on learning about biologics and biosimilars. This conference would be your single best opportunity to reach the largest assemblage of participants from the biologics and biosimilars community.

**Abstract Information: Oral / Poster Presentation Guidelines**

Oral Presentations are generally split into TWO categories, as follows:

1. Plenary Lectures
   - Each Plenary lecture is 25 minutes in length and comprises one presentation. We recommend you plan to present for approximately 20 minutes with 5 minutes for questions/discussion.
   - Where Plenary Lectures are presented as debates, each of two speakers should plan to present for 20 minutes, allowing five minutes for closing questions and conclusions. We recommend that invited speakers communicate in advance of the Moderator so that presentations may be coordinated.

2. Oral Sessions
   - Each Oral Session is 60 minutes in length and comprises two presentations, of 30 minutes each. We recommend that you plan to present for approximately 15 minutes, allowing time for questions/discussion at the end of the presentation.

Please prepare your presentation in 16:9 format (screen are in format 16:9). We recommend you to save your PowerPoint presentation using PPT(X) format instead of PPS.

A technician is available in every session room to provide assistance when needed. Due to the online presentation system, all speakers are kindly requested to use provided PC onsite. Please be present in the session room 15 minutes prior the start of your session and follow the instructions from the Chairs and/or technician. During your presentation a remote control will be available for controlling your presentation. Please observe the time allotted to you as you will not be permitted to speak for longer time. At the end of the Congress, all presentations will be deleted from the presentation system and computers on-site.

**Speaker Preview Room**

All speakers are asked to upload their presentation at the Speaker Preview Room (located in the Registration area) at least one hour before the beginning of the session or the day before in case of a morning session.
**Poster Guidelines**

The poster exhibition will be an integral part of Med Pharma Congress. The poster exhibition will be located on the exhibition area of the congress centre. The area will be clearly signposted from the registration area.

Technical Instructions:
- Posters must be prepared in Portrait style.
- Please DO NOT prepare a landscape poster
- The dimensions should be 100 cm high by 70 cm wide
- Posters should be attached to the boards with stickers, which you will be supplied to the organizers.
- Poster session schedule Posters will be displayed and presented in session.

Please plan to be at your poster and available to answer questions from delegates at the time of your assigned poster session. Posters will be displayed according to the POSTER numbers given by the organizers and will be grouped by sub topic.

**Young Researchers Forum**

The Young Researchers Forum offers young researchers the possibility to meet and discuss research topics and methodologies, share and develop ideas, learn from each other and gain knowledge from senior researchers.

Young Researcher Sessions are organized at the Med Pharma Congress, to provide a unique platform for Young Researchers/Investigators for presenting latest research projects with an in-depth analysis. Young Investigators (e.g. Post-Graduate students, Post-doctoral fellows, Trainees, Junior faculty) are the focus of this event. Participants should be below the age of 33 years. All submissions must be in English.

The prize winning papers will be considered for publication in the international journals once the paper is subjected to standard review procedures.

For further information please contact: biosimilarsasia@pharmaceuticalconferences.org
Registration Information

How To Register
Website: http://biosimilars-biologics.pharmaceuticalconferences.com/asiapacific//registration.php

Registration Fees

- Early registration fee: $799
- (SAVE $100.00 — DEADLINE: May 25, 2017)
- Regular registration fee: $899
- SAVE $100.00 — February 28, 2017 through June 27, 2017)
- Late registration fee: $999
- Discounts on Group Registrations
- Student Registration: $249
- Young Researchers Forum Fee: 399$

Cancellation Policy

Cancellations must be received in writing 60 days prior to the meeting and are subject to a $100 processing fee. Refunds will not be granted after April 03, 2017, nor will they be given for no-shows. Please email cancellations to biosimilarsasia@pharmaceuticalconferences.org

Accommodations

Double Tree by Hilton Beijing
168 Guang An Men Wai Avenue Xi Cheng District,
Beijing 100055
China

To make reservations and ensure that you will have a hotel room at the same location as the conference, please choose your package and register at http://biosimilars-biologics.pharmaceuticalconferences.com/asiapacific//registration.php

Payments

We accept Visa, Master Card, American Express and checks. If paying by credit card, please utilize our online registration site located at http://biosimilars-biologics.pharmaceuticalconferences.com/asiapacific//registration.php
If you wish to pay by check, please contact biosimilarsasia@pharmaceuticalconferences.org
For more information:
Questions? Contact 1 (800) 216 6499 or inquiries: biosimilarsasia@pharmaceuticalconferences.org
Register now at http://biosimilars-biologics.pharmaceuticalconferences.com/asiapacific//

Stay Connected Before, During and After the Event!
Day 1: August 10, 2017

Opening Ceremony
Conference Souvenir Launch
New Perspective frontiers in the area of Biologics and Biosimilars
Keynote Forum (& Exhibitions Full day)
(Panels discussions and Reviews)
Coffee Break: Networking & Refreshments
Group Photo

Speaker Forum
Sessions Chair’s Introduction
Track 1: Latest Biosimilars in Asian Scenario
Track 2: Biosimilars- Hatch-Waxman Act & BPCI Act
Track 3: Challenges in Developing Biosimilars
Track 4: Biosimilars Research Pipeline
Track 5: Current Developments in The Field of Biosimilars
Panel discussions and Reviews

Lunch Break
Young Research Forum
(Panels discussions and Reviews)
Coffee Break: Networking & Refreshments
B2B Meetings
Certificates Felicitation by the organizing Committee

Day 2: August 11, 2017

Introduction
Keynote Forum (& Exhibitions Full day)
(Panels discussions and Reviews)
Coffee Break: Networking & Refreshments

Speaker Forum
Sessions Chair’s Introduction
Track 6: Pharmacovigilance of Biosimilars
Track 7: Emerging Trends in Biosimilars
Track 8: Biosimilars Market - Challenges & Prospects
Track 9: Cost Analysis of Biosimilars
Track 10: Globalization of Biosimilars
Panel discussions and Reviews

Lunch Break
Young Research Forum
(Panels discussions and Reviews)
Coffee Break: Networking & Refreshments
B2B Meetings
Certificates Felicitation by the organizing Committee

Day 3: August 12, 2017

Introduction
Keynote Forum (& Exhibitions Full day)
(Panels discussions and Reviews)
Coffee Break: Networking & Refreshments

Speaker Forum
Sessions Chair’s Introduction
Track 11: Biosimilars Analytical Strategies
Track 12: Emerging Biosimilars in Therapeutics
Track 13: Clinical Studies on Biosimilars
Track 14: BCS & IVIVC Based Biowaivers
Track 15: Entrepreneurs Investment Meet
Panel discussions and Reviews
Young Research Forum
(Panels discussions and Reviews)

Lunch break
Speaker Sessions (Cont...)
Poster Sessions Evaluation by the Committee
Refreshments
Award Ceremony
Felicitation of the best poster awards

Closing Ceremony
Glimpses of Biosimilars 2016
Media Partners @ Asian Biosimilars 2017

- Bentham Science
- Bio-Equip
- BioPharma Asia
- Clinical Biometrics Solutions Limited
- eindiabusiness.com
- Haptic
- BioNanonet
- AntibodyChain
- EIN Presswire
- Farmavita
- Allied Academies
- New York Private Equity Forums
- Andrew John Publishing Inc.
- Pharmaceutical-Tech.com
- Pharma Focus Asia
- The Pharma Times
- Trade Show Alerts
- ManuscriptEdit
Plan your Trip to Beijing

7 UNESCO World Heritage Sites

Forbidden City

Grand Canal

Great Wall

Ming Tombs

Summer Palace

Temple of Heaven

Zhoukoudian

Forbidden City
About Beijing

Beijing (formerly Romanized as Peking) is the capital of the People's Republic of China and the world's third most populous city proper. It is also one of the world's most populous capital cities. Beijing is the second largest Chinese city by urban population after Shanghai and is the nation's political, cultural, and educational center. It is home to the headquarters of most of China's largest state-owned companies, and is a major hub for the national highway, expressway, railway, and high-speed rail networks. The Beijing Capital International Airport is the second busiest in the world by passenger traffic. The city's subway network is among the longest and busiest in the world. The city is renowned for its opulent palaces, temples, parks, gardens, tombs, walls and gates, and its art treasures and universities have made it a center of culture and art in China.

Beijing has seven UNESCO World Heritage Sites – the Forbidden City, Temple of Heaven, Summer Palace, Ming Tombs, Zhoukoudian, as well as parts of the Great Wall and the Grand Canal. Beijing hosted the 2008 Summer Olympics and was chosen to host the 2022 Winter Olympics, which will make it the first city to ever host both events.

Beijing's primary airport is the Beijing Capital International Airport (IATA: PEK) about 20 kilometers (12 mi) northeast of the city center. The airport is the second busiest airport in the world after Hartsfield-Jackson Atlanta International Airport. After renovations for the 2008 Olympics, the airport now boasts three terminals, with Terminal 3 being one of the largest in the world. Most domestic and nearly all international flights arrive at and depart from Capital Airport. It is the main hub for Air China and a hub for China Southern and Hainan Airlines. The airport links Beijing with almost every other Chinese city with regular air passenger service.

Contact Details
http://biosimilars-biologics.pharmaceuticalconferences.com/asiapacific
Submit your abstract online at:
Register online:
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