THE BIOSIMILARS GROUP

POWER BY MULTIPLICITY

27 JANUARY 2016

BIOSIMILARS DEVELOPMENT - FROM PRE-CLINIC TO MARKET

Several biological products, altogether worth over US$60 billion annual sales, are encountering patent expiry by 2020. This opens up the opportunity for many biotech and pharma companies to emerge as strong competitors in the biosimilar development market.

During this half-day conference, we will bring together several experts from the industry and academia, covering critical stages and presenting opportunities and challenges associated to the development of biosimilars.

Areas covered will include:

- Pre-clinical development
- Pharmacokinetics/Pharmacodynamics
- Regulatory requirements for biosimilars devolpment
- Clinical monitoring of marketed biosimilars
- Extrapolation of indications
- Marketing approval pathways and challenges

WED, 27 JANUARY 2016
1:00 pm – 6.00 pm

Quadriga Forum Berlin
Werderscher Markt 13
10117 Berlin

REGISTRATION: 99€

THE BIOSIMILARS GROUP
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Register by **23 January 2016** online at
www.thebiosimilarsgroup.com/biosimilars-development-from-pre-clinic-to-market/
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Invited Speakers

Prof. Dr. João Gonçalves

João Gonçalves, PharmD, is head of the Bio-pharmaceutical Biotechnology Unit and Antibody Engineering Lab at iMed and Instituto de Medicina Molecular and is Professor of Immunology and Biotechnology at the Faculty of Pharmacy, Lisbon. He received a PhD in Infectious Diseases/Immunology from Harvard and Lisbon Universities and a Pharmaceutical Medicine management post-graduation from the Univ. of California. He worked on antibody research at Centocor, Scripps Research Institute and Genentech. His research focuses on therapeutic antibody discovery and development.. He is member of the Portuguese Pharmacopoeia Commission, Portuguese Commission of Medicines Evaluation and member of the editorial board of several scientific journals. He has authored >100 scientific papers.

Dr. Gundel Hager

Coming from the Max Planck Institute, München, Dr. Gundel Hager has accompanied the successful preclinical development of many substances at Aurigon Life Science: classic small molecules, ATMPs and CBMPs, food additives, vaccines, as well as biologics and biosimilars.
In addition to being the CEO of Aurigon GmbH, Dr. Hager is involved in various pre-clinical development projects, where the vast experience she acquired throughout her career is of great value.
Furthermore, Dr. Hager is actively involved in training and development within the academic community.

Prof. Dr. Bernd Jilma

Professor Dr. Bernd Jilma, M.D., is Associate Professor of Clinical Pharmacology & Internal Medicine at the Medical University of Vienna, where he received his medical license.
Along with his position at the University of Vienna, Prof. Dr. Jilma is expert and scientific advisor of AGES and EMA committees and President of the Clinical Pharmacology Section of the Austrian Pharmacologic Society.
He has been accumulating expertise in clinical research since 2001 as Principal Investigator, in Phase I-III trials, as well as being part of international data safety monitoring boards.
Besides his >300 publications in peer reviewed journals, Prof. Dr. Jilma has himself been reviewer for >80 journals.

Isabelle Racamier

Isabelle Racamier holds a master's degree from the Paris based ESCP Europe Business School. After holding management positions in France, Switzerland, the USA and Japan, Isabelle Racamier came to Austria in 1998 as the General Manager of Sanofi, where she worked for seven years.
In 2007 she created Urban Living, a company specialized in the development of historical buildings.
Later, Isabelle founded Arlys Consulting - a company specialized in advising companies in Life Sciences - where she currently works as the Managing Director.
Isabelle Racamier is currently living in Vienna with her two sons.

Dr. Petra Schmitt

Dr. Petra Schmitt, initially trained as veterinarian, has several years of experience in the field of physiology and oncology at international research institutes. From 2007-2015 she was preclinical and clinical assessor for biologics and biosimilars at the Paul-Ehrlich-Institute, one of the federal regulatory agencies in Germany. Her work included assessment of clinical trial application with focus on early development, PK/PD and first-in-man studies, centralized marketing authorization applications, contribution to national and EMA scientific advice procedures and regulatory guidelines. Furthermore, she was a member of the EMA Modeling and simulation working group (MSWG). Recently, she joined the regulatory strategy department of PharmaLex GmbH.

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PROGRAMME

13:00 – 13:30 Registration and Welcome Coffee

13:30 – 13:40 Welcome

13:40 – 14:25 *Non-clinical Development of Biosimilars*
Dr. Gundel Hager – Aurigon GmbH

14:25 – 14:55 *Pharmacokinetic/pharmacodynamic considerations for biosimilars*
Prof. Dr. Bernd Jilma – Medical University of Vienna, Department of Clinical Pharmacology

14:55 – 15:40 *Developing biosimilar antibodies with optimized critical quality attributes*
Prof. Dr. João Gonçalves – Faculty of Pharmacy of Lisbon; iMed.ULisboa

15:40 – 16:10 Coffee Break

16:10 – 16:55 *Market access – a challenge?*
Isabelle Racamier – Arlys Consulting GmbH

16:55 – 17:40 *Points to consider for extrapolation of indications for biosimilars*
Dr. Petra Schmitt – PharmaLex GmbH

17:40 – 17:50 Final remarks and closing of event

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