Conference

FORUM

Biosimilars 2017

The latest information on development, marketing authorisation and market access/healthcare management

Your speakers

Dr Niklas Czeloth
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, GERMANY

Head of Biosciences, Biosimilars

Dr Steffen Groß
Paul-Ehrlich-Institut (PEI), Langen, GERMANY

Dr Bernd Liedert
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, GERMANY

Senior Clinical Program Leader Biosimilars

Dr Gareth Morgan
Olswang LLP
London, UNITED KINGDOM

Partner

Thomas Müller
Federal Joint Committee (G-BA), Berlin, GERMANY

Head of Pharmaceuticals Department

Dr Steffen Schuy
Boehringer Ingelheim Pharma GmbH & Co.KG, Ingelheim, GERMANY

Device & Combination Product Development Manager, Global Bioprocess & Pharmaceutical Development

Dr Elena Wolff-Holz
Paul-Ehrlich-Institut (PEI)
Langen, GERMANY

Chair BMWP

Dr Robert E. Zoubek
Granzer Regulatory Consulting & Services, Munich, GERMANY

Senior Consultant

21 – 22 June in Frankfurt/Offenbach

Wednesday, 21 June 2017

09.00

Regulatory update from the EU Biosimilar Medicines Working Party

Dr Elena Wolff-Holz

- Update on Biosimilars in the EU
- Has regulatory thinking concerning interchangeability and substitution changed?
- Consequences of recent switch studies
- New formulations introduced by the reference: implications for the claim of similarity and interchangeability

10.30 Coffee break

10.45

Substitution with biosimilars – the healthcare point of view

Thomas Müller

- Substitution and interchangeability – nationally and in the EU
- Substitution at the pharmacy or prescription level: experience with the German G-BA aut idem directive
- Incentives for the use: reference pricing, quotas, therapy advice?
- Comparative benefit assessment of biological drugs in rheumatoid arthritis

11.45

Discussion round: Biosimilars in Europe

Dr Elena Wolff-Holz, Thomas Müller, Dr Bernd Liedert

- Biosimilars as part of the tender business in parts of Europe: are there consequences for Germany?
- Being better but still similar: new formulations, optimised posology, improved devices and the regulators', clinicians' and payers' perspectives

12.15 Lunch

13.30

Key considerations for combination product/device development

Dr Steffen Schuy

- What is a medical device from the non-regulatory and the regulatory viewpoint?
- Pre-filled syringes and autoinjectors for biosimilars
- Crash course in design control
- Design verification and validation
- Human-factors engineering

14.30

Clinical studies to support device development

Dr Bernd Liedert

- Population, design, endpoints:
  - Human-factor studies
  - Pharmacokinetic bridging studies
  - Real-life patient handling studies

15.30 Coffee break

16.00

Extrapolation of indications

Dr Bernd Liedert

- Level of evidence for known, plausible and hypothetical modes of action
- Post-authorisation data for indications not specifically studied
- The IBD community and extrapolation for TNF antagonists
- Still a challenge: extrapolation of immunogenicity for high-risk biosimilars

17.00 End of day one

Thursday, 22 June 2017

09.00
Biosimilars in the US
Dr Robert E. Zoubek

- Status quo of the interchangeability guideline
- Naming requirements
- Labelling obligations
- Biosimilars in the US healthcare system

10.30 Coffee break

10.45
Analytical development of biosimilars
Dr Niklas Czeloth

- Methods to assess physico-chemical and biological activity of biosimilars
- General assay requirements to cover similarity and structure–function relationship
- FDA tiering and statistical concept
- Immunogenicity testing: methodological considerations

12.00 Lunch

13.15
Comparability exercises and (non-)acceptance of differences
Dr Steffen Groß

- Experiences and case studies

14.30
Patents in the context of biosimilars
Dr Gareth Morgan

- Patent litigation on biosimilars
- Managing product protection life cycles
- SPC “squatting” on third-party products
- Future strategies for patentees of biologics molecules

15.30 End of conference

Aims and objectives

Do you work in biosimilars or intend to do so? Then you should not miss this conference with leading biosimilars experts. During the two conference days, you will receive a full update from development requirements, to marketing authorisation requirements through to reimbursement topics.

I would be very pleased to welcome you on the 21 June at the conference!

Dr Henriette Wolf-Klein
Department Manager
Pharma & Healthcare

Who should attend?

This conference addresses the needs of managers in the pharmaceutical industry who work with biosimilars.

Those working in the following areas will particularly benefit from this event:

- Marketing authorisation
- Clinical and preclinical development
- CMC/quality and analytics
- Market access and business development
- Legal affairs/patent protection

Registration: +49 6221 500 555 or email: service@forum-institut.de

Yes, I will attend the conference

☐ Biosimilars 2017

Name

Position/Department

Company

Street address

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

- **Registration: +49 6221 500-500**
- **Conference-No. 17 06 231**
- **Date/Venue:**
  21 - 22 June 2017
  1st day: 08.30 registration; 9.00-17.00 conference
  2nd day: 09.00 - 15.30 conference
  Sheraton Offenbach
  Berliner Str. 111 · 63065 Frankfurt/Offenbach
  Tel. +49 69 82999-0 · Fax +49 69 82999-800
- **Fee:**
  € 1,890.00 (+German VAT) incl. course documentation (incl. free download) as well as midsession refreshments, lunch and certificate.
- **Questions and information:**
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- **Cancellation Policy:**
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