Seminar

FORUM

Biosimilars FORUM

Topics

- Comparability exercise – the reference as a “moving target”
- Quality issues: quality target product profile
- Clinical testing: bioequivalence, immunogenicity
- Sourcing of originator medication
- Biosimilars: guidelines, current regulatory thinking and health economics

Biosimilars challenges – the EU, the US & the ICH region

Your speakers

Dr. Ute Essner
O.MEANY Consultancy GmbH,
Hamburg, GERMANY

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

Dr. Bernd Liedert
Merck Serono,
Darmstadt, GERMANY

Dr. Christian Schmitz
Multipharma GmbH,
Berlin, GERMANY

Dr. Michael Sych
Granzer Regulatory Consulting & Services, Munich, GERMANY

Dr. Martina Weise
Senior Expert Regulatory Affairs,
Bonn, GERMANY

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

2 - 3 July 2014 in Frankfurt

Aims and objectives

We would like to give you a thorough update on the new challenges and opportunities arising in connection with the revision of the overarching biosimilars guideline and further guidelines/revisions.

During the two-day seminar you will receive valuable information on comparability exercises, bioequivalence and immunogenicity testing, as well as in-depth information on quality issues. Further economic factors related to pricing and reimbursement will be addressed to complete the picture.

After having attended this seminar you will be familiar with the current regulatory requirements and will have a good insight into the European, the US and further development programmes. You will know about the main development challenges and will have new ideas on how to overcome them.

Who should attend?

This seminar addresses the needs of managers in the pharmaceutical industry who work with biosimilars or plan to do so in the near future.

Especially those working in the following areas will benefit from this event: marketing authorisation, clinical & preclinical trials, quality & analytics, business development and law.

Limited number of attendees

This seminar is restricted to 30 participants. This limitation, a feature of all FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

Chair of the Seminar

Dr. Bernd Liedert

Merck Serono, Darmstadt, GERMANY

Director, Head of Immunopharmacology Oncology, Merck Serono – Exploratory Medicine

Your speakers

Dr. Ute Essner

O. MEANY Consultancy GmbH, Hamburg, GERMANY

Director

Dr. Steffen Gross

Paul-Ehrlich-Institut (PEI), Langen, GERMANY

Dr. Christian Schmitz

Multipharma GmbH, Berlin, GERMANY

Business Development Manager

Dr. Michael Sych

Granzer Regulatory Consulting & Services, Munich, GERMANY

Senior Consultant

Dr. Martina Weise

Senior Expert Regulatory Affairs, Bonn, GERMANY

Dr. Weise has outstanding experience with regard to Diabetes and Biosimilars and is a member of various European advisory boards

Dr. Elena Wolff-Holz

Paul-Ehrlich-Institut (PEI), Langen, GERMANY

Your programme

Additional time for networking in the breaks included

2 July: 9h00 - 17h00

Regulatory update
Dr. Martina Weise

- Revised guidelines at the outset of 2014:
  - "Overarching" guideline on similar biological medicinal products
  - Non-clinical and clinical issues
  - Recombinant human insulin and insulin analogues
- Challenges during the review process

Pillars of the comparability exercise
Dr. Steffen Gross

- Do's and don'ts
- The reference as a "moving target"
- Acceptance of reference drugs sourced from outside your own region
- Essentials in the comparability documentations
- Lowering the amount of preclinical and clinical data needed by optimising the comparability exercise in the future?

The revised guideline on quality issues
Dr. Steffen Gross

- Purpose of the quality target product profile (QTPP) in biosimilar development
- Recommendations on different/novel expression systems
- Post-approval quality changes – drift in the profile of the originator product and impacts on the biosimilar

Clinical testing phase I: demonstration of bioequivalence
Dr. Bernd Liedert

- Parallel versus crossover design
- Average, population and individual bioequivalence
- Average bioequivalence: acceptance margins
- Calculating sample size
- Most suitable study population for PK analyses
- How far does "bio-equivalence" need to go?
- Pharmacodynamics studies within Phase I?

Biosimilars – current regulatory thinking
Dr. Elena Wolff-Holz

- Current regulatory thinking on biosimilars
- Extrapolating indications
- Sensitive clinical endpoints
- Risk management and pharmacovigilance
- Considerations for biosimilars labelling
- Experiences with the first biosimilar mAb (Remsima/Inflectra)

3 July: 9h00 - 15h30

Biosimilars development programmes – the EU, the US and the ICH region
Dr. Michael Sych

- Update – US FDA follow-on biologics approach
- Biosimilars in other regions – establishing a worldwide development programme?
- Impact of the latest biosimilar marketing authorisations on the worldwide development programmes

Challenges in sourcing of originator medication at pre-clinical and clinical stages
Dr. Christian Schmitz

- Innovator industry defence strategy: Restricted access to reference compounds intended as comparator in biosimilars studies
- How to find variety of different lots or originator medication from different markets for the analytical dossier?
- A logistical challenge: synchronising of GMP manufacturing and procurement of reference compound
- Challenges: import and export of biological and RMPs
- US versus EU specific challenges
- Issues with certain products

Biosimilars and health economics
Dr. Ute Essner

- Mature markets
- Cost savings – what can be expected?
- Factors with an impact on pricing and reimbursement
- Can biosimilars be as cheap as traditional chemical generics?
- What drives the biosimilar uptake?
- Incentives/Quotas/Restrictions?
- Developing countries
- Biosimilars – an option for those who cannot afford originators?

Clinical immunogenicity testing in practice
Dr. Bernd Liedert

- Immunogenicity: A risk-based approach
- Susceptibility of immunogenicity to changes in quality attributes: comparability, compatibility and formulation
- Design aspects: eligible population, duration and power
- Dealing with improved immunogenicity profiles
- Interferon ß: a first attempt to harmonise immunogenicity testing
- Impact of immunogenicity on exposure: population pharmacokinetic analyses
- Non-comparative post-marketing surveillance of immunogenicity

Registration recommended 30 days in advance

Registration under
service@forum-institut.com or
Fax +49 6221 500-555

Registration Form

Yes, I will attend the seminar
☐ **Biosimilars FORUM**

☐ I am interested in receiving more information on FORUM events an agree that this information be sent to me by e-mail.

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

How to register

- Registration: +49 6221 500-501
- Conference-No. 14 07 231

Internet:
www.forum-institut.com

Date/Venue:
2 - 3 July 2014
Day 1: 8h30 registration; 9h00 - 17h00 seminar
Day 2: 9h00 - 15h30 seminar
Hilton Frankfurt Hotel
Hochstr. 4 · 60313 Frankfurt
Tel. +49 69 13380-2230 · Fax +49 69 13380-6030

Fee:
€ 1.790,– (+ German VAT)
The fee includes course documentation (incl. free download) as well as midsession refreshments, lunch and certificate. Invoice and confirmation will be forwarded to you.

Hotel accommodation:
A limited number of rooms have been reserved at the hotel and are subject to availability. Please book at least six weeks prior to the seminar to obtain a hotel room at the discounted rate. All bookings should be made directly with the hotel quoting Forum-Institut and the Seminar-No.

Any further questions?

I am gladly at your disposal should you have any further questions about the seminar.

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Cancellation Policy

Our general terms and conditions apply (as of 1. December 2011) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.de/agb_en