Seminar

FORUM

Biosimilars, Biobetters & Synthetic Scaffold Molecules

Topics

- Revision of the EU biosimilar guidelines – an update
- mAb – EU guideline update & immunogenicity assessment
- The FDA follow-on biologics approach
- Intellectual property rights
- Quality changes & comparability exercises

Regulatory update: EU & USA

Your speakers

Dr. Ulrich Granzer

Granzer Regulatory Consulting & Services,
Munich, GERMANY

Dr. Bernd Liedert

Merck Serono,
Darmstadt, GERMANY

Dr. Steffen Gross

PEI,
Langen, GERMANY

Dr. Christian Schneider

Danish Health and Medicines Authority,
Copenhagen, DENMARK

Dr. Gareth Morgan

Winston & Strawn LLP,
London, UNITED KINDGDOM

Dr. Martina Weise

BfArM,
Bonn, GERMANY

21 -22 November 2012 in Cologne

Aims and objectives

Is it possible from a regulatory point of view that a biosimilar is better than the original – "biobetter"?

At the seminar this and other challenging questions will be addressed by experts from the industry and various competent authorities.

What is the current regulatory framework for biosimilars in the EU and in the US, what are the expectations regarding the upcoming guidelines?

May we invite you to take part in this meeting to get firsthand information on the regulatory issues as well as on practical points such as

- product characterisation
- comparability exercises
- the current intellectual property rights and much more?

Who should attend?

This seminar addresses the needs of managers in the pharmaceutical industry. Especially those working in the following areas will benefit from this event:

- Marketing authorisation
- Clinical and preclinical research
- Quality & analytics
- Law & intellectual property rights

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.

Your speakers

Dr. Ulrich Granzer

Granzer Regulatory Consulting & Services, Munich, GERMANY

Owner

Dr. Steffen Gross

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

Dr. Gareth Morgan

Winston & Strawn LLP, London, UNITED KINDGDOM

Partner in the London office of Winston & Strawn's intellectual property department

Dr. Bernd Liedert

Merck Serono, Darmstadt, GERMANY

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

Dr. Christian Schneider

Danish Health and Medicines Authority, Copenhagen, DENMARK

Senior Medical Officer, Chair of the Biosimilar Medicinal Products Working Party (BMWP)

Dr. Martina Weise

Federal Institute for Drugs and Medical Devices (BfArM), Bonn, GERMANY

Head of the Unit Diabetes Mellitus/Cardiovascular System, Vice-Chair of the Biosimilar Medicinal Products Working Party (BMWP), German CHMP Alternate

Your programme

21 Nov. 2012: 9.30 - 17.30

Biobetters & synthetic scaffold molecules – the future of biosimilars?
Dr. Ulrich Granzer

- Biobetters, what makes them different to biosimilars?
- Synthetic scaffold molecules: advantages and issues

Revision of the biosimilar guidelines – an update
Dr. Martina Weise

- Revision of the overarching biosimilar guideline
- Revision of the guideline on similar biological medicinal products containing biotechnology-derived proteins as their active substance: non-clinical and clinical issues
- Update regarding the product-specific biosimilar guidelines

Monoclonal biosimilars
Dr. Christian Schneider

- The final guideline on similar biological medicinal products containing monoclonal antibodies: clinical endpoints; non-inferiority versus equivalence trials
- Immunogenicity assessment of monoclonal antibodies: comparative immunogenicity testing

Biomarkers, surrogates etc – minimising and optimising the study programme?
Dr. Ulrich Granzer

Synthetic scaffold molecules & “biobetters” – always a stand-alone marketing authorisation?
Dr. Martina Weise, Dr. Christian Schneider

Compliance with the intellectual property rights in the EU
Dr. Gareth Morgan

- IP compliance regarding the reference product
- SPCs on biologics - impact of current decisions from the CoJ
- Patent protection possibilities for biosimilars

The new FDA follow-on biologics approach
Dr. Ulrich Granzer

- Is “abbreviated” really a short pathway for the marketing authorisation of biological products?

An introduction to the new US biosimilar patent litigation pathway
Dr. Gareth Morgan

22 Nov. 2012: 9.00 - 15.00

Guideline on similar biological medicinal products
Dr. Steffen Gross

- Origin and formulation of the reference product
- Biological characterisation
- Comparative pharmacodynamics: receptor binding studies and cell-based assays for monoclonals
- Revision of the quality guideline, physicochemical characterisation

Quality changes & comparability exercises according to the CHMP guidance documents
Dr. Steffen Gross

- Variation regulation and the need for comparability exercises?
- Consequences of process changes on the quality attributes and subsequently on the safety and efficacy of drug products

Preclinical and clinical comparability exercises
Dr. Bernd Liedert

- Changes in quality attributes that trigger pre-clinical and clinical comparability exercises
- EMA & FDA regulatory frameworks that cover pre-clinical and clinical comparability exercises
- Need for non-clinical and clinical studies – a risk-based and stage of development-based approach
- Value and limitations of preclinical PK, PD and tox analyses
- How to demonstrate comparability at the clinical level: bioequivalence, efficacy, safety and immunogenicity
- Biosimilarity vs. comparability exercises: What are common features, where are the differences?

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

Registration Form

Yes, I will attend the Seminar

☐ **Biosimilars, Biobetters & Synthetic Scaffold Molecules**
21 - 22 November 2012 in Cologne

☐ I am interested in more information about FORUM-Events and I agree that this information is 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-Information:
FORUM · Institut für Management GmbH
POB 10 50 60 · D-69040 Heidelberg

Registration: +49 6221 500-501
Seminar-No. 12 11 232

Internet:
www.forum-institut.de

Date/Venue:
Day 1: 9.00 registration, 9.30 - 17.30 seminar
Day 2: 9.00 - 15.00 Seminar
Dorint am Heumarkt
Pipinstr. 1 · 50667 Köln
Tel. +49 221 2806-0 · Fax +49 221 2806-1111

Fee:
€ 1.590,– (+ 19 % VAT)
The fee includes course documentation as well as mid-session refreshments and lunch. 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 four weeks prior to the seminar to obtain a hotel room at the discounted fee. 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