Workshop

FORUM

Biosimilar Development Workshop

Topics

- Critical quality attributes
- Abbreviated study programme: extrapolating indications
- Similarity testing and interchangeability
- Biobetter elements and cost-saving supplements
- Comparability to pre-change product and originator

Recent cases in biosimilar clinical development and use will be discussed

Your speakers

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

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

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

27 March 2019 in Frankfurt am Main

Biosimilar Development Workshop

Aims and objectives

This workshop gives you a thorough update on recent challenges in biosimilar development. Quality, clinical and non-clinical issues will be discussed with reference to recent cases.

It will also provide you with a toolbox for improving your biosimilar development and the ability to position your product.

Who should attend?

This workshop addresses the needs of healthcare professionals involved in the development, marketing authorisation and market access of biosimilars.

A working knowledge of biosimilar development is a prerequisite.

Limited number of attendees

This workshop is limited to 20 participants. This limitation, a feature of all FORUM seminars, enables participants to thoroughly discuss the complex issues covered by the programme.

Your speakers

Dr Steffen Groß
Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Langen

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

Dr Elena Wolff-Holz
Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Langen

Your benefits

- Three absolute experts in biosimilars to engage with.
- Current cases in biosimilar development (in the EU and US) will be discussed in detail.
- All crucial development issues will be addressed.

Your programme 09:00 - 17:00

> 09:00

Critical quality attributes

Dr Steffen Groß

- Defining an adequate QTPP
- Quality development as the basis for biosimilar development
- Statistical approaches
- Functional characterisation
- How much deviation from the originator is acceptable?

> 10:15

Avoiding non-clinical in vivo studies

Dr Steffen Groß

- In vitro characterisation

> 10:45 Coffee break

> 11:00

Biosimilar clinical development

Dr Elena Wolff-Holz

- Is abbreviated development permitted?
  - Guidelines
  - Valid surrogates
  - Equivalence or non-inferiority
  - Exceptions
- Extrapolation of therapeutic indications
  - 'Totality of evidence' concept
  - Clinical development in the field of oncology
- Immunogenicity and interchangeability
  - EMA regulatory requirements and thinking
    - Guideline
    - Which assay format is valid?
  - Selected examples

> 12:30 Lunch

> 14:00

Innovation in biosimilar clinical development and use - recent cases to be discussed

Dr Bernd Liedert

- Similarity testing of critical quality attributes lead to the set-up of advanced methods initially established for comparability exercises
- Regulatory view of the clinical relevance of pharmacological assays may affect granting of similarity status and extrapolation
- Rituximab biosimilars: off label phase III model "low-tumour burden follicular lymphoma" for demonstration of clinical similarity
- Demonstration of interchangeability between Cyltezo and Humira
- Infliximab biosimilar Remsima: biobetter elements on top of biosimilar status
- Infliximab biosimilar Remsima: a therapeutic drug monitoring kit as a cost-saving supplement

> 15:30 Coffee break

> 16:00

Life cycle of biosimilars

Dr Steffen Groß

- Comparability (to pre-change product and originator)
- How to keep your product a biosimilar

> 17:00 End of workshop

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

Registration Form

Yes, I will attend the Workshop
☐ Biosimilar Development Workshop

☐ Yes, I agree that FORUM Institut may inform me about events and relevant expert content by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

Position, department

Company

Street

Post code, city, country

Tel. no.

E-mail

Contact person at office

Date, signature

How to register

- **Registration: +49 6221 500-500**
- **Conference no.: 19 03 233**

- **Website:**
www.forum-institut.com

- **Date and venue**
Wednesday, 27 March 2019 in Frankfurt am Main
08:30 registration; 09:00 – 17:00 course
FLEMING´S Express Hotel Frankfurt
Poststraße 8 · 60329 Frankfurt am Main
Tel. +496927391-0 · Fax +496927391-999

- **Fee**
€ 1090.00 (+ German VAT)
The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

Any Further Questions?

Please feel free to contact me if you have any questions.

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Cancellation Policy

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