Seminar

FORUM

RUSSIA: Registration of Generics and Biosimilars

Topics

- Legal background for a generic registration
- Current challenges in biosimilar registrations
- Dossier and registration process
- Local bioequivalence studies according to the new Russian guidelines

Local bioequivalence and tox studies required!

Your speakers

Marika Pečená, M.D.
Vice President,
Quinta Analytica,
Czech Republic

Dr. Edelgard Rehak
Regulatory Director Sanofi Russia; Medical Director Zentiva Russia

30 January 2015 in Berlin

RUSSIA: Registration of Generics & Biosimilars

Aims and objectives

Since the introduction of Federal Law 61 in 2010 for registrations of medicinal drug products in Russia, local clinical trials have been mandatory. This has led to an increase in local bioequivalence studies.

On the other hand the number of drug registrations is decreasing. The hurdles for generic registrations are very high and cost intensive.

This seminar provides you with an update on the current regulatory requirements when applying for a registration (biosimilars or generics). You will be informed of your duties regarding the dossier and application process and learn in detail how to fulfill the requirements arising through the new bioequivalence guidelines.

Who should attend?

This seminar addresses the needs of co-workers of the pharmaceutical industry who intend to register generics and/or biosimilars in Russia or support the registration process by providing the essential data.

The seminar is especially interesting for

- clinical affairs
- medical affairs
- regulatory affairs people.

Your speakers

Marika Pečená, M.D.

Vice President,
Quinta Analytica,
Czech Republic

Dr Pečená graduated in human medicine from Charles University Prague. She has worked in the pharmaceutical industry for more than 15 years and has broad experience in Gx development and regulatory projects in Russia and in Central and Eastern Europe.

Dr Pečená has been engaged in Russia since 2011, actively building local environments in bioequivalence studies. In addition she has broad experience with regulatory strategy and generic portfolio development.

Dr. Edelgard Rehak

Regulatory Director Sanofi Russia; Medical Director Zentiva Russia

Dr Rehak is an expert for registrations in Russia and in Central and Eastern Europe. She has worked as Regulatory Director Sanofi and Medical Director Zentiva based in Moscow from 2011 to 2014 and from 2006 until 2009 as Head Regulatory and QA for Novartis based in Kiev, Ukraine.

She has broad experience in bioequivalence and toxicological trials in Russia. Until 2006 she worked in various functions in product development (Gx and biosimilars) and clinical research at Sandoz/HEXAL in Germany.

Local bioequivalence and tox studies required!

Your programme from 9h00 - 17h00

The legal background for a biosimilar/a generic registration in Russia

- Environment and legal background

The registration process

- Timelines
- Structure and cooperation with the health authorities

Dossier content

- Administrative documentation
- Package information leaflet
- Normative documentation
- Clinical documentation
- Nonclinical documentation

Current challenges in generic/biosimilar registrations

- Registration strategies for Gx
- Registration of biosimilars
- How to find the right service provider?

Toxicological trials for Gx applications

Local bioequivalence studies

- Current Russian guidelines in bioequivalence studies
  - Comparison of the (2008) guideline and the new (2013) guideline - impact of differences in PK parameters between these two guidelines
  - Comparison of the new guidelines with the European guidelines
- Current situation in clinical operations in BE studies: Practical examples and different point of views
- Discussing issues with designing BE studies in Russia
- Discussion on efficacy parameters in BE studies - do we really need them?
- How to find the right service provider in Russia?

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

Registration Form

Yes, I will attend the seminar
☐ RUSSIA: Registration of Generics and Biosimilars

☐ I am interested in receiving more information on FORUM events and 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 500-500**
- **Conference-No. 15 01 234**

Internet:
www.forum-institut.com

Date/Venue:
Friday, 30 January 2015 in Berlin
8h30 registration; 9h00 – 17h00 seminar
Leonardo Royal Hotel Berlin Alexanderplatz
Otto-Braun-Straße 90 · 10249 Berlin
Tel. +49 30 755430-0 · Fax +49 30 755430-810

Fee:
€ 990.00 (+ German VAT)
The fee includes course documentation (incl. free download) as well as mid-session 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 Course No.

Any Further Questions?

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

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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.com/t&c