Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES

FORUM

Getting Biosimilars on the US Market

Topics

- Marketing authorisation approval at the FDA
- Getting ready to launch
- Prelaunch activities under the Bolar amendment
- Patent dispute resolution under the Biosimilar Act
- Practical tips for the US biosimilar applicant

How the FDA Biosimilar Guidances and the Biosimilar Act affect your business

Your speakers

Jill M. Browning
GREENBLUM & BERNSTEIN, P.L.C., Reston, Virginia, USA

Dr Walter Schlapkohl
GREENBLUM & BERNSTEIN, P.L.C., Reston, Virginia, USA

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

25 October 2017 in Munich

Getting Biosimilars on the US Market

Aims and objectives

Do you intend to bring your biosimilar products to the US market? Then you should not miss out on this seminar. Three experts provide first-hand knowledge on things you should do with regard to:

- regulatory affairs; and
- legal affairs and IP.

After having attended the seminar you will be aware of the current regulatory framework in the US and know the pitfalls you should avoid in order to launch your products on time.

Who should attend?

This seminar should be of interest to all in the pharmaceutical industry involved in bringing their biosimilar products to the US market. In particular, those working in regulatory affairs, market access and legal affairs/IP will benefit from the experts' first-hand knowledge.

Limited number of attendees

This seminar 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

Jill M. Browning
GREENBLUM & BERNSTEIN, P.L.C., Reston, Virginia, USA

Partner, Patent Attorney

Dr Walter Schlapkohl
GREENBLUM & BERNSTEIN, P.L.C.
Reston, Virginia, USA

Partner, Patent Attorney

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

Senior Consultant

Your learning outcomes

Knowledge of:

- The current Biosimilar Guidance
- The current challenges in dealing with the US FDA in terms of naming, labelling, etc.
- The requirements for interchangeability
- Your legal obligations in terms of pre-marketing activities
- The details of the Biosimilar Act and the implications of current court decisions
- Strategies for bringing your products to the US market

Your programme 09.00 - 17.30

> 9.00
Biosimilar Act overview
Jill M. Browning, Dr Walter Schlapkohl

> 10.00
Working with the FDA to obtain a marketing authorisation approval
Dr Robert E. Zoubek

- Organisation of the FDA
- Biosimilar Guidances
- FDA meetings, data requirements, GDUFA fees
- National specialities: interchangeability, naming, labelling

> 11.15 Coffee break

> 11.30
Getting ready to launch - patent strategy
Jill M. Browning, Dr Walter Schlapkohl

- Bolar amendment: how much protection is offered to prelaunch activities?
- How to locate problematic patents
- Patent dispute resolution under the Biosimilar Act
  - Overview
  - Compared to Hatch-Waxman ANDA challenges
- Guidance from the courts regarding the Biosimilar Act
  - Amgen vs Sandoz
  - Amgen vs Apotex
- Alternative ways to challenge patents (PTAB Proceedings)

> 12.45 Lunch

> 14.00
Continuation: Getting ready to launch - patent strategy
Jill M. Browning, Dr Walter Schlapkohl

> 15.30 Coffee break

> 15.45
State activities
Dr Walter Schlapkohl

> 16.30
Possible patent strategies for the US biosimilar applicant
Jill M. Browning, Dr Walter Schlapkohl

- Getting your own patents
- Patent eligible subject matter

> 17.15 Final discussion

> 17.30 End of seminar

Registration under
formacion@qualitecfarma.com or
Telf.: +34 91 372 83 99

Registration Form

Yes, I will attend the seminar
☐ Getting Biosimilars on the US Market

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

How to Register

Registration: +34 91 372 83 99

Conference No. 17 10 233

Internet:
www.qualitecfarma.com

Date / Venue:
Wednesday, 25 October 2017 in Munich
08.30 registration; 09.00 - 17.30 seminar
Leonardo Hotel Munich Arabellapark
Effnerstr. 99 · 81925 Munich
Tel. +49 89 92798-0 · Fax +49 89 983813

Fee:
€ 1090.00 (+ 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 accommodations:
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 January 2016) 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