Seminar

FORUM

Marketing Authorisation Outside the ICH Region

Topics

- Who follows the ICH or WHO principles?
- Submission strategy based on CPP?
- Role of affiliates, external consultants and agents
- Dossier, submission and maintenance duties
- Rolling out submissions

Tips for your regulatory strategy in international markets

Your speakers

Dr Bettina Fiedler
Bayer Pharma AG, Berlin

Ayaz Hameed Khan
Grünenthal GmbH, Aachen

Dr Stefanie Lietsch-Dallwig
PharmaLex GmbH, Mannheim

27 February 2015 in Köln

Marketing Authorisation Outside the ICH Region

Aims and objectives

Getting ready for business on international markets, including those in the non-ICH region? Then you shouldn't miss out on this seminar.

Here you will get practical tips on which regions/countries enforce which requirements and where you might want to seek external help in regulatory affairs questions.

After having attended this seminar you will be able to define your regulatory strategy and have a deeper knowledge on the current challenges in the various regions of the world.

Who should attend?

This seminar addresses the needs of regulatory affairs professionals with marketing authorisations outside the EU or aiming for new marketing authorisations worldwide.

It is also useful for business development, clinical affairs and medical affairs professionals.

A working knowledge of the European marketing authorisation system is assumed.

Your speakers

Dr Bettina Fiedler
Bayer Pharma AG, Berlin

Global Regulatory Affairs EEMEA

Ayaz Hameed Khan
Grünenthal GmbH, Aachen

Director, Regulatory Affairs | IRPL - GRA, Global Regulatory Affairs

Dr Stefanie Lietsch-Dallwig
PharmaLex GmbH, Mannheim

Regional Project Management

Limited number of attendees

This seminar is restricted to 20 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.

Tips for your regulatory strategy in international markets

Your programme 9.00 - 17.00

> 9.00

Regulatory affairs outside the ICH region - the key principles

Dr Bettina Fiedler

- Regions/Countries following the Q, E, S ICH guidelines
- Countries following the WHO guidelines
- Countries solely referring to European or US marketing authorisation
- The difficult ones: those with their own approach

> 10.00

Countries with or without CPP requirements

Ayaz Hameed Khan

- Overview of CPP-dependent and non-CPP-dependent countries
- Regulatory submission strategy based on CPP
- Potential parallel filings in emerging markets
- Marketing authorisation recognition

> 11.00 Coffee break

> 11.15

Marketing authorisation application - with external help!

Ayaz Hameed Khan

- Role of affiliates and agents in global submission strategies
- External consultants, third-party evaluations and local scientific support in submissions and getting a marketing authorisation
- Health agency interactions in non-EU countries and their impact on regulatory strategy

> 12.15 Lunch

> 13.30

Marketing authorisation dossier - CTD/eCTD

Dr Stefanie Lietsch-Dallwig

- CTD, always according to the ICH requirements?
- Transition to eCTD or other electronic submissions
- Further requested documents in addition to the dossier (product information, GMP certificate, ...)

> 14.45

Maintenance duties

Dr Stefanie Lietsch-Dallwig

- Variations system in place? Renewals necessary?
- Pharmacovigilance duties

> 15.30 Coffee break

> 16.00

Regulatory strategy

Dr Bettina Fiedler

- Which regions first, from a regulatory affairs point of view?
- Rapid roll-out of submissions to the international markets

> 17.00 Seminar end

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

Registration Form

Yes, I will attend the seminar
☐ Marketing Authorisation Outside the ICH Region

☐ 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 02 234**

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

- **Date/Venue:**
Friday, 27 February 2015 in Köln
8.30 registration; 9.00 - 17.00 seminar
Pullman Cologne
Helenenstr. 14 · 50667 Köln
Tel. +49 221 275-0 · Fax +49 221 275-2205

- **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