Seminar

QualitecFarma®
REGULATORY & BUSINESS STRATEGIES

FORUM

The EU Regulatory Affairs Expert

Topics

- National peculiarities in European procedures
- Brexit and regulatory affairs challenges
- Current PV topics: PRAC recommendations, PASS/PAES, RMP
- Regulatory optimisation: variations and eSubmission
- EU and national OTC switch initiatives
- Co-marketing and co-promotion - regulatory considerations

Fine-tune your regulatory affairs expertise

Your speakers

Dr. Peter Bachmann
Senior Expert Regulatory Affairs, Bonn, GERMANY

Dr. William Shang
Johnson & Johnson GmbH, Neuss, GERMANY

Stan van Belkum
Medicines Evaluation Board, Utrecht, NETHERLANDS

6 December 2017 in Amsterdam

The EU Regulatory Affairs Expert

Aims and objectives

Do you work in regulatory affairs and have solid EU regulatory affairs knowledge?

Then you should not miss this seminar. The EU Regulatory Affairs Expert seminar will address the current challenges in EU regulatory affairs, including dealing with national peculiarities (also in EU procedures), regulatory optimisation challenges, your duties with regard to Brexit and much more.

After having attended this seminar, you will be aware of the current regulatory trends in the EU, you will know how to prepare for an OTC switch and how to fulfil your PV obligations, and you will be able to prepare your regulatory part for Brexit.

Who should attend?

This seminar addresses the needs of regulatory affairs workers in the pharmaceutical industry. Those with a solid basis in European procedures will particularly benefit from this seminar.

Your benefits

- Three regulatory affairs experts from the industry and from national authorities share their expertise with you in a full-day seminar.
- Advanced practical information will be obtained.
- Issues beyond your own specific area will be addressed.

Your speakers

Dr. Peter Bachmann
Senior Expert Regulatory Affairs, Bonn, GERMANY

He has many years' experience in regulatory affairs. He made a significant contribution to establishing the European DCP System.

Dr. William Shang
Johnson & Johnson GmbH, Neuss, GERMANY

Director Regulatory Affairs

Stan van Belkum
Medicines Evaluation Board, Utrecht, NETHERLANDS

Deputy Director
Stan van Belkum has been working in the international arena of global harmonisation of electronic standards for more than 10 years and was one of the founders of the eCTD in ICH. He currently leads the Regulatory Optimisation Group, a spin-off from the HMA Multi Annual Working Plan.

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 programme

> 09:00

National peculiarities in European marketing authorisation procedures

Dr Peter Bachmann

- Well-established use - throughout Europe?
- Similar assessment of generic and WEU applications
- Challenges in the national phase

> 10:00

Brexit - your regulatory affairs duties to fulfil by March 2019

Dr Peter Bachmann, Dr William Shang

- Change of RMS - when is it necessary?
- National marketing authorisation in UK - when is it necessary?
- Considerations for companies
  - Smooth implementation: stakeholders and deadlines

> 11:15 Coffee break

> 11:30

Current PV procedures and the regulatory consequences

Dr Peter Bachmann

- PRAC recommendations and referrals
- Conditions for the marketing authorisation approval and the practical consequences
  - PASS/PAES
  - RMP
  - Educational material

> 12:30 Lunch

> 13:45

Regulatory optimisation and e-driven challenges

Stan van Belkum

- Goals of the Regulatory Optimisation Group
- Facilitation of the variations system
- Linkage to the eSubmission roadmap

> 15:00 Coffee break

> 15:30

Varying prescription status (Rx/OTC) throughout Europe

Dr William Shang

- Obstacles to self-medication and OTC switches in the EU:
  - Improving the switch process? EU and national OTC switch initiatives
  - Changing the OTC switch environment? Opportunities and challenges

> 16:15

Co-marketing and co-promotion - regulatory aspects

Dr William Shang

- From due-diligence to the market: role of regulatory affairs
- Regulatory considerations for CP and DCP/MRP
- Roles and responsibilities of co-marketing partners

> 17:00 Seminar end

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

Registration Form

Yes, I will attend the seminar

☐ The EU Regulatory Affairs Expert

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 12 235

Date / Venue:

Wednesday, 6 December 2017 in Amsterdam
08:30 registration; 09:00 - 17:00 seminar
Renaissance Amsterdam Hotel
Kattengat 1 · NL 1012 Amsterdam
Tel. +31 20 62 12 223 · Fax +31 20 62 75 245

Fee:

€ 1,090.00 (+ 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.

Pablo García
Conference Manager
Tel. +34 91 372 83 99
formacion@qualitecfarma.com

Cancelation Policy

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