Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES

FORUM

Marketing Authorisation in ASIA

Topics

- Current regulatory framework in the Asian countries
- ASEAN: Harmonisation of the Asian drug market?
- China – guidelines and marketing authorisation
- Marketing authorisation for NCEs and generics
- Submission of variations and renewals
- Communication with the authorities

Focus: China, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, Vietnam

Your speakers

Dr. Alan A. Chalmers
Pharma International, Innovation Centre, SWITZERLAND

Dr. Mónica Dressler-Meyer
Consultant for Regulatory Affairs, Binningen, SWITZERLAND

24 – 26 October 2017 in Mannheim

Marketing Authorisation in ASIA

Introduction:
24 October
09.00 – 13.00

Aims and objectives

You are interested in receiving and maintaining a marketing authorisation in Asia? Then you shouldn't miss this seminar!

After having completed this seminar you have an in-depth insight into the current regulatory framework of the various countries. Two experts will give you valuable information regarding

- dossier requirements
- communication with the authorities
- marketing authorisation procedures
- maintenance duties

and inform you about future developments in the ASEAN region.

If you are in need of basic know-how, we recommend attending the introductory seminar on day one. Here you will be informed in detail about the various regions of Asia, including in-depth information on China and the ASEAN countries.

Who should attend?

This seminar will be of benefit to all those working in the pharmaceutical industry and interested in marketing pharmaceuticals in Asia. Especially those working in regulatory affairs and business development will profit from the seminar.

Participants in need of basic know-how regarding the Asian market will especially benefit from the introductory seminar on day one.

This seminar is restricted to 20 participants.

Your speakers

Dr. Alan A. Chalmers
Pharma International, Innovation Centre, SWITZERLAND

Director, consultancy on international regulatory affairs. His main expertise lies in the field of pharmaceutical regulatory affairs. He has a 35 years' experience, especially with a focus on Asia (first in national pharmaceutical companies later as an international consultant).

Dr. Mónica Dressler-Meyer
Consultant for Regulatory Affairs, Binningen, SWITZERLAND

She has several years' experience in regulatory affairs in the Asia – Pacific area, most recently as DRA Manager FE Countries at a Swiss pharmaceutical company.

Day 1: Introductory seminar
24 October: 09.00 – 13.00

The Asian markets: an overview
- Commerce in Asia; cultural specialities

ASEAN countries – background information and newest developments
- Initiatives for the harmonisation of the Asian drug market
- Newest developments and perspectives in drug registration
- Conclusions for marketing authorisation in Asia

Marketing authorisation in CHINA – introduction to the Chinese Market

Advanced seminar: Marketing Authorisation in ASIA

Day 1:
China
24 October: 14.00 – 18.00

CHINA – Guidelines and marketing authorisation procedures in detail

- Company registration and marketing authorisation
- Marketing authorisation application for NCEs
- Variation and renewal procedures
- Communication and meetings with the authorities

Summary of day 1 and networking apero with the speakers

Day 2:
Philippines, Taiwan, Korea
25 October: 09.00 – 17.00

PHILIPPINES

- Marketing authorisation & maintenance

HONG KONG

Conditions for a marketing authorisation in TAIWAN

- Regulatory framework
- Authority structure
- Maintenance of the marketing authorisation

KOREA
(Republic of Korea/South Korea)

- Marketing authorisation & maintenance

Day 3:
Thailand, Malaysia, Indonesia
26 October: 09.00 – 17.00

Regulatory framework in THAILAND

MALAYSIA and VIETNAM

- Marketing authorisation & maintenance

Regulatory framework in INDONESIA

Requirements in SINGAPORE

ASEAN countries

- Future developments in the ASEAN countries
- Summary of the seminar

Time schedule:

- Introductory seminar
  24 October 09.00 – 13.00

- Advanced seminar
  24 October 14.00 – 18.00
  25 October 09.00 – 17.00
  26 October 09.00 – 17.00

The advanced seminar can be booked separately!

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

Registration Form

Yes, I will attend the Seminar

- ☐ Introductory+advanced seminar (3 days)
- ☐ Advanced seminar (2,5 days)

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 10 231

Date / Venue:
24 – 26 October 2017 in Mannheim
Radisson BLU Hotel
Q7, 27 · 68161 Mannheim
Tel. +49 621 8607 42 42 · Fax+49 621 8607 4249

Fee:
€ 2,390.00 (+ German VAT)
Introductory + advanced seminar = 3 days

€ 1,990.00 (+ German VAT)
Advanced seminar = 2.5 days
The fee includes course documentation (incl. free download) as well as mid-session refreshments, lunch, networking apero 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
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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