SEMINAR

FORUM 40 YEARS

Marketing Authorisation in ASIA

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

TOPICS

- Current regulatory framework
- 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

YOUR SPEAKERS

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

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

22 - 24 OCTOBER 2019 IN MANNHEIM

Marketing Authorisation in ASIA

Intoduction:
22 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 and
- 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. He is the Qualified Person (FvP) for several Swiss pharmaceutical companies.

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

22 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

Your programme day 1:

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

The participants are warmly invited to also contribute their own experiences for a thorough exchange! Please send your topic, question, ... at least 10 working days before the start of the seminar to Dr Henriette Wolf-Klein (h.wolf-klein@forum-institut.de).

Your programm day 2:

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
- Regulatory Environment

Your programm day 3:

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

Marketing Authorisation in ASIA

REGISTRATION UNDER

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REGISTRATION FORM

Yes, I will attend

☐ Introductory + advanced seminar (3 days)

☐ Advanced seminar (2,5 days)

☐ Yes, I agree that FORUM Institut may inform me about events by: ☐ email; and/or ☐ telephone. I may withdraw my consent at any time.

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

Date and venue
22 - 24 October 2019 in Mannheim

Introductory seminar:
Day 1 (22.10.2019): 09:00-13:00
Advanced seminar
Day 1 (22.10.2019): 14:00-18:00
Day 2 (23.10.2019): 09:00-17:00
Day 3 (24.10.2019): 09:00-17:00

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Fee
€ 1,990.00 (+ German VAT) = 2,5 days
€ 2,390.00 (+ German VAT) = 3 days

The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

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CANCELLATION POLICY

Our general terms and conditions (as of 1 January 2016) apply and are available upon request.
We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

PharmaTrain MASTERING MEDICINES DEVELOPMENT CENTRE RECOGNITION

TRUSTPILOT

YOUR CONTACT

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