Pharmaceutical Regulatory Affairs in China

Also covering Hong Kong, Macau and Taiwan

20-21 November 2019 Basel, Switzerland

Benefits of attending:

- Gain an overview of the regulatory procedures in the region
- Understand and assess the impact of recent regulatory reforms
- Discuss clinical product development and Chinese-specific approaches
- Understand requirements for import and local manufacture registration
- Discuss product registration strategies

Expert faculty:

Dr Alan Chalmers
Director, Pharma International, Switzerland

Monica Dressler-Myer
Regulatory Consultant, Switzerland

‘This course was well paced and met my needs in terms of content and interactivity. Both speakers were extremely knowledgeable and approachable which I believe is important in this setting.’

Chris Dodd, Mexichem UK Ltd

Pharmaceutical Regulatory Affairs in China

To book online go to: management-forum.co.uk/1672

Date and venue
20-21 November 2019 Ref: 10572
Radisson SAS Hotel
Steinentorstrasse 25
Basel CH-4001
Switzerland
Tel: +41 61 227 29 75

Programme schedule
Registration and refreshments: 09.00
Day one: 09.30-17.00
Day two: 09.00-17.00

Accommodation
To take advantage of this, please contact the hotel and state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment.

Email: reservations.basel@radissonblu.com
Web: www.radissonblu.com/basel

For information on alternative accommodation, please visit our website: management-forum.co.uk/accommodation

Three ways to book
management-forum.co.uk @ info@management-forum.co.uk +44 (0)20 7749 4730

Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 4 October 2019
£1299.00 • €1819.00

FULL PRICE Book AFTER 4 October 2019
£1499.00 • €2099.00

Multiple booking discount for 2nd or subsequent delegates - 15%
£1274.15 • €1784.15

Payment options
1. Invoice which can be paid by bank transfer or credit/debit card
2. Online through our secure website when registering

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Coming to Management Forum for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

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FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements, please advise customer services when booking.

PLEASE NOTE: Management Forum Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Management Forum will refund the registration fee and disclaim any further liability.

For event cancellation policy and T&Cs see our website
This seminar will provide an invaluable overview of how to gain and maintain a successful pharmaceutical marketing authorisation in the People’s Republic of China (PRC), including Hong Kong, Macau and Taiwan. The two-day course will cover:

- All important aspects of gaining and maintaining a successful marketing authorisation in the region
- Recent regulatory reforms
- Drug regulatory systems
- An overview of import and local manufacture registration
- Clinical product development including CMC regulatory requirements
- An interpretation of practical aspects
- The opportunity to exchange experiences with other delegates

Who should attend?

This seminar will be of particular interest to all those who need to learn about successful marketing authorisation applications and in-market regulatory compliance in this region. You will find this seminar useful both as an introductory or refresher course.

Previous delegates have included scientists and technical staff in regulatory affairs and registration departments, medical directors, and personnel from analytical research and development, clinical development, quality assurance, new business development and regulatory authorities.

Why you should attend

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- The opportunity to exchange experiences with other delegates

Expert faculty

Dr Alan Chalmers, BSc, PhD, MRPharmS is Director of Pharma International in Switzerland, consulting for various companies, organisations and authorities. He has over 35 years’ pharmaceutical experience, mainly in international pharmaceutical regulatory affairs. He is also a Qualified Person with several smaller Swiss companies.

Monica Dressler-Myer is a DRA Manager in Switzerland. She has worked for several major companies in this role and also has links to Swissmedic (Swiss Regulatory Agency). She has a Degree in Chemistry from Basel University.

Previous attendees have said:

‘Excellent speakers, helpful discussions during the sessions and breaks.’
Thorben Bonarius, Siegfried AG

‘The course was good with a lot of valuable information.’
Robert Klasson, Xellia Pharmaceuticals ApS

Programme

### Day one

- **Introduction and welcome**
- **General introduction to the PRC and the pharmaceutical market**
  - Commercial and cultural background
- **Drug regulatory systems**
  - Regulatory authorities
  - Recent regulatory changes
  - Regulations and guidelines
  - Drug classification systems
  - Import and local manufacture registration
  - Data requirements
  - Registration requirements
  - Labelling requirements
- **Clinical product development**
  - Regulatory aspects of clinical development
  - Recent regulatory changes
  - Documentation needs including CMC
  - Regulatory requirements including GCP aspects
  - Chinese-specific approaches
  - Multinational clinical trials

### Day two

- **PRC**
  - Product registration strategies
  - Summary information contrasting import and local manufacture registrations
  - Planning to meet documentation requirements
  - Expediting regulatory approvals
- **CMC regulatory requirements**
  - Brief overview of CMC-related issues
  - Variations and renewals
  - Regulatory procedures
  - Documentation expectations
- **Taiwan (Republic of China)**
  - Cultural background
  - Regulatory authorities
  - Regulations and guidelines
  - Drug classification systems
  - Data requirements
  - Country-specific matters
- **Hong Kong SAR**
  - Background overview
  - Regulatory authorities
  - Regulatory requirements and procedures
  - Specific market aspects
- **Macau SAR**
  - Brief overview of regulatory aspects
- **Discussion session**

A certificate of attendance for professional development will be available to each participant who completes the course.

Management Forum in-house training

If you would like to discuss running this or any other course on an in-house basis, please call Aleksandra, our in-house training expert, on +44 (0) 20 7749 4730 or email inhouse@management-forum.co.uk

To find out more, please visit: management-forum.co.uk

Three easy ways to book

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