IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Pharmaceutical Regulatory Affairs in Asia

9-11 October 2024

This seminar will provide an overview of the key areas of pharmaceutical regulatory affairs in Asia including, China, Hong Kong SAR, Brunei, the Philippines, India, Indonesia, Malaysia, Singapore, Thailand, Cambodia, Laos, Vietnam, Taiwan, Korea, Japan

Format:
Live online

CPD:
18 hours for your records

Certificate of completion

Course Overview

The pharmaceutical market in Asia is growing at a rapid pace and presents both opportunities and challenges to those wishing to work in the region. Rather than a single market, Asia is a collection of different markets, each with their own regulatory processes, although harmonisation exists within the ASEAN countries.

This seminar will provide a practical overview of the key areas of pharmaceutical regulatory affairs in Asia, including India, and will cover all important aspects of gaining and maintaining a successful marketing authorisation within the region.

The programme will include:

- Discussion of underlying official regulatory sources
- An interpretation of practical aspects
- An overview of the requirements for local manufacturing
- Recent developments
- Harmonisation initiatives
- An update and wider knowledge of regulatory affairs in Asia
- The opportunity to exchange experiences with other delegate

Benefits of attending:

- **Gain** an overview of key Asian markets
- **Discuss** outlines of company and product registration
- **Understand** the application process
- **Assess** the impact of recent regulatory developments in the region
- **Discuss** harmonisation initiatives including ASEAN opportunities
- **Understand** how Japan fits in the Asian regulatory landscape
- **Discover** general, country-specific and regional requirements

Please note that the course will provide an excellent introduction to all the key aspects of regulatory affairs in the Asia region but will not focus specifically or in detail on Chemistry, Manufacture and Control (CMC).

Programme

The programme consists of regional presentations covering:

- **The markets**
  - Brief commercial and cultural background
  - Importance of major markets
- **Company and product registration**
  - Regulations and guidelines
  - Drug classification systems
  - Site registration
  - New products
  - Line extensions
  - Labelling changes
  - Sourcing changes
  - Registration samples
  - Certificates/legalisation
- **Application process**
  - Committees/meetings
  - New applications
  - Variations
  - Renewals/re-registration
- **Recent regulatory developments**
  - Influences and changes: national and regional
  - The latest regulatory developments in the region

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, whether as an introductory or a refresher course.

Previous delegates have included:

- Scientists and technical staff in
  - Regulatory affairs
  - Registration departments
- Medical directors

Programme

Day 1

Introduction to the Asia Region

Introduction to ASEAN

Philippines

Brunei

PR of China

Day 2

India

Malaysia

Singapore

Hong Kong

Indonesia

Thailand

Vietnam / Cambodia / Laos

Day 3

Taiwan

Korea

Outline on Japan

Asean Harmonisation

Presenters

Monica Dressler-Meyer

Mónica Dressler-Meyer is DRA Manager based in Switzerland with many years of regulatory experience. She has spent many years in DRA working with different pharmaceutical companies with responsibility for Asia Pacific and lately also for development activities in other regions. Prior to this, she worked at F. Hoffmann-La Roche in Switzerland where she gained several years' experience in industry basics and pre-clinical research. She has a Degree in Chemistry and Biochemistry from Basel University.

Alan Chalmers

Dr Alan Chalmers is a pharmacist with over 35 industrial experiences mainly in the field of pharmaceutical regulatory affairs. A graduate of Strathclyde University in Glasgow with a B.Sc. in Pharmacy with specialisation in Pharmaceutical Technology, his Ph.D. at Manchester University was in Pharmaceutical Formulation. From 1975-1978 he was Development Officer and Clinical Trials Pharmacist of Allen & Hanburys (part of the then Glaxo group). In 1978 he joined Ciba-Geigy in DRA. Over 20 years were spent with Ciba-Geigy/CIBA/Novartis in all aspects of regulatory affairs including head of a group company DRA in Canada and for many years as Head of Pharma International regulatory affairs.

He has been consultant to the IFPMA, WHO and other international bodies and was Chairman of the Organising Committee of the initial IFPMA Asian Regulatory Conferences in Hong Kong and Singapore and Rapporteur to the more recent conferences in China and Malaysia.

Since 1998 he has been an independent regulatory consultant and is Director of his own consultancy company Pharma International in Switzerland. He has also been director of two UK and Swiss registered pharmaceutical companies with specialised responsibility for international regulatory strategy. More recently as accredited by Swissmedic, Dr. Chalmers is a Qualified Person supporting several Swiss pharmaceutical companies trading internationally with pharmaceuticals and medical devices.

He is published, and his publications include a textbook on *International Pharmaceutical Registration*, *Active Pharmaceutical Ingredients* and as Swiss correspondent to the Regulatory Affairs Journals Pharma and Medtech. Since 2012 he has been a member of the Editorial Board, *Scrip Regulatory Affairs*.

Course date

9-11 October 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 13933*	GBP **1,349** ~~1,649~~ EUR **1,939** ~~2,359~~ USD **2,201** ~~2,669~~ **Until 04 Sep**

How to book

Online:
ipi.academy/2055

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) 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, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Alan and Monica have presented very detailed information on all regulatory aspects. Their knowledge is exceptional and very useful to this webinar.

Srinivas Parimi
Regulatory Affairs Manager - Rest of Asia Pacific
PharmaCare Laboratories Pty Ltd
Jun 14 2023

★★★★★

The webinar was fantastic as all seminars I attend with Management Forum UK. I will only attend the programs at management forum regarding country regulatory affair systems as they have been the most thorough and realistic programs in my 28 years of the pharma industry. I look forward to the next one.

Angela Turner
RA Director

Nov 15 2021

★★★★☆

Both are very experienced on these countries with high knowledge on the regulatory aspects. I can say that my opinion of the course is very positive.

Sonia Dias
Regulatory Affairs Officer
BIAL - Portela & Ca, S.A.
Apr 24 2019

★★★★☆

I think the content is very good, even though very extensive

Karina Kück
Graduate Regulatory Professional
H. Lundbeck A/S
Apr 24 2019

Run this programme in-house for your whole team

Coming to IPI Academy 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.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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