IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Pharmaceutical Regulatory Affairs in China

25-26 June 2025
+ 26-27 November 2025

A detailed overview of the key areas of pharmaceutical regulatory affairs in China, Hong Kong, Macau and Taiwan.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

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

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

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.

Programme

Day 1

General introduction to the PRC and the pharmaceutical market

- Commercial and cultural background

P.R. China - 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

P.R. China - 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

Hong Kong SAR

- Background overview
- Regulatory authorities
- Regulatory requirements and procedures
- Specific market aspects

Macau SAR

- Brief overview of regulatory aspects

Day 2

P.R. China - Regulatory Strategies

P.R. China - Health Authority Interactions

P.R. China - Maintenance

Taiwan (Republic of China)

- Cultural background
- Regulatory authorities
- Regulations and guidelines
- Drug classification systems
- Data requirements
- Country-specific matters

P.R China - Recent Developments

Presenters

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*.

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.

Course dates

25-26 June 2025	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 14793*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 21 May**
26-27 November 2025	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 15142*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 22 Oct**

How to book

Online:
ipi.academy/1672

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

Email:
info@ipiacademy.com

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

★★★★★

Very clear, interesting and worth it!

Mélissa Cardenas Trujillo
Regulatory Affairs & Registrations Specialist I
Laboratoires Thea Sas
Apr 29 2024

★★★★☆

Valuable Webinar and very good interactions with the speakers.

Celine Aubertin
International Regulatory Affairs Manager
NOOUS FINANCE AU NOM ET POUR LE COMPTE DE PIERRE FABRE SA
Dec 10 2024

★★★★☆

I would highly recommend [...] I appreciate there were more than one speaker to change it up and make the different topics more varied to listen in on. Also very nice how the speakers would supplement each other when responding to questions

Maria Mikkelsen
Regulatory CMC Specialist
Ascendis Pharma
Nov 22 2022

★★★★☆

I would highly recommend

Maria Mikkelsen
Regulatory CMC Specialist
Ascendis Pharma
Nov 22 2022

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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