IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Pharmaceutical Regulatory Affairs in China

25-26 November
+ 19-20 May 27, 24-25 November 27

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 two-day webinar offers a comprehensive review of Pharmaceutical Regulatory Affairs in China. It provides participants with the essential knowledge and understanding of the regulatory requirements for conducting clinical trials in the People's Republic of China (PRC) and for registering pharmaceutical products for the Chinese market.

While the primary focus is on the PRC, the webinar also covers regulatory frameworks in Hong Kong (Special Administrative Region), with brief insights into Macau. Detailed information is provided regarding the registration of pharmaceutical products in both PRC and Taiwan (Republic of China, ROC).

This course also examines pharmaceutical maintenance and other regulatory matters, primarily focusing on innovative products, while including relevant information about generic products.

The programme combines real-world case studies with practical guidance, drawing from the speaker's own professional experience to explore theoretical scenarios. Participants are encouraged to enrich the discussion by sharing relevant company insights, where appropriate and permitted

Please note: This webinar does **not** cover Medical Devices, Immunology drugs, or Vaccines.

Benefits of attending

- **Gain** access to a wealth of information, which would otherwise be time-consuming to research
- **Exchange** practical experiences with peers and professionals
- **Examine** relevant case studies based on real challenges and opportunities
- **Enhance** knowledge and seek reassurance in solving day-to-day regulatory problems
- **Participate** in frequent Q&A sessions that contribute to enhanced know-how and understanding
- **Receive guidance** on optimising the handling of regulatory situations and challenges

Who should attend

Primarily, this webinar is intended for Pharmaceutical Regulatory Affairs professionals interested in working with China (PR China, including the Hong Kong SAR and Macau SAR), as well as Taiwan (Republic of China), to receive updates on recent developments and to exchange information or seek guidance on current challenges.

Regulatory Affairs professionals who are new to dealing with China and the region, and who require extensive background information and training.

This webinar may also be of interest to other team members from related line functions, including:

- Marketing
- Medicine
- Logistics
- Production, etc., to gain a general overview and introduction

Programme

Day 1

Presentation of participants

Quiz

Drug regulatory systems

Clinical product development

Hong Kong

- Regulatory authorities
- Regulatory procedures and requirements
- Focus on pharmaceutical products
- Information sources
- Brief clinical trial aspects
- Future trends

Macau

- Brief overview of regulatory environment
- Regulatory authorities
- Regulatory requirements
- Future trends

Day 2

Product registration strategies

- Outline of regulatory strategy options
- Historical development and current opportunities
- Practical challenges

Case studies

Variations

HA Interactions

TAIWAN Republic of China

Recent developments

Q&A and quiz

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 dates

25-26 November	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 16576*	GBP **1,499** EUR **2,099** USD **2,399**
19-20 May 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17213*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 24 Mar**
24-25 November 27	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 17516*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 29 Sep**

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 **30% 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

★★★★★

I hoped to receive an overview of the regulatory landscape in CN and received a very deep overview of the regulatory landscape in the mentioned countries with a lot of facts and knowledge for CN and the territories HK, MO and TW + CN :). I learned a lot and could answer my questions as a take home message.

Susanne Klitzke
Regulatory Affairs Manager
Merz Therapeutics
Jun 25 2025

★★★★★

Very dynamic and engaging presentations. I wanted to gain a general understanding of the structure of the Chinese agency and its various functions, as well as the overall process for finished product registration. I'm truly pleased with the information that was shared — it fully met my expectations. The materials were very comprehensive, containing a wealth of information on the topic and very well organized. The speakers were highly knowledgeable and had a broad perspective on the topic. It was very interactive, making participation easy and encouraged. The platform was excellent in facilitating communication during the presentation.

Montserrat Megias Barrera
RA Manager
inke
Jun 25 2025

★★★★★

Very clear, interesting and worth it!

Melissa 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

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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