IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Global Pharmaceutical Regulatory Affairs Summer School

10-14 June 2024 / 17-19 June 2024 / 24-27 June 2024 / 2-3 July 2024

Unlock the world of pharmaceutical regulatory excellence with our Global Pharmaceutical Regulatory Affairs training – an intensive journey through the diverse regions, offering practical insights, expert guidance, and strategic mastery for professionals seeking to navigate and succeed in the dynamic global regulatory landscape.

Format:
Live online

CPD:
84 hours for your records

Certificate of completion

Overview

Navigate the ever-changing landscape of pharmaceutical regulations worldwide and ensure compliance by attending our Global Pharmaceutical Regulatory Affairs course – an indispensable resource for professionals seeking to stay current, mitigate risks, and thrive in the dynamic global pharmaceutical environment.

In an industry defined by evolving complexities, staying ahead is not just an advantage, but a necessity. This intensive summer school ensures a 360-degree understanding of global regulatory dynamics and has been designed to allow comprehensive exploration of regulatory landscapes in key regions.

Our expert-led courses provide practical insights, interactive case studies, and strategic guidance, equipping you with the knowledge to navigate diverse regulatory environments. Participants will not only grasp theoretical concepts but also hone the skills required to implement them in real-world scenarios.

This Summer School is made up of the following modules, the EU, Asia, Africa, Latin America, Russia & the Eurasian Union, the Middle East, and China. You can attend the entire Summer School, or mix and match modules to best suit your professional needs.

Please contact us for pricing of bespoke modules, info@ipi.academy.

Benefits of attending

- **Gain** a holistic understanding of regulatory affairs across diverse global regions.
- **Acquire** practical insights through case studies and discussion.
- **Receive** expert guidance from seasoned trainers with regional expertise.
- **Learn** to develop regulatory strategies for product approval in diverse markets.
- **Understand** regulatory reforms and updates.
- **Explore** regulatory authorities and requirements.

Who should attend?

- Pharmaceutical Regulatory Affairs Personnel
- Project Managers
- Clinical Development Professionals
- Business Planners
- Commercial Management Professionals
- Manufacturing Professionals
- Technical Staff
- Quality Assurance/Quality Control

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 various regions around the world. You will find this seminar useful both as an introductory or refresher course.

Programme

Day 1

Module 1: EU Pharmaceutical Regulations & Strategy

EU Regulatory Environment: Legal Basis

- Key regulations, directives and guidelines
- Impact of Brexit
- Proposed EU pharmaceuticals legislation (specific changes will be discussed in the relevant section of the programme)

Information Sources

Case Study One

Development and Strategy

- Drug discovery
- Scientific advice

Development Process

- Pharmaceutical R&D
- Non-clinical tests
- Clinical studies - Phase I to III

EU Clinical Trials Regulation

Types and Categories of Marketing Authorisations

Adaptive Marketing Authorisation Procedures

The Common Technical Document (CTD)

- Overview of Structure and content of a CTD

Procedures for obtaining a Marketing Authorisation in the EU with discussion on the impact of Brexit and the proposed EU Legislation Changes

Other EU Centralised Procedures

- Referral and arbitration

Day 2

Other Procedures for Obtaining a Marketing Authorisation in the EU

Managing Product Labelling

Case Study Two

Abridged Applications and Generics

Product Life Cycle: Post approval

Patents and SPCs

Parallel Trade

- How the process works
- Impact of Brexit

Post-authorisation Obligations; Pharmacovigilance, Variations and Renewals

Pharmacovigilance including discussion on the impact of Brexit

Licence Variations

- Type I and Type II variations and timelines
- Procedures and timelines

Extensions

Case Study Three

Renewals

Sunset Clause

Phase IV Trials

Classification Change

Generic Development

Strategic Factors

Criteria for Successful Products

Day 3

Module 2: Pharmaceutical Regulatory Affairs in Asia

Introduction to the Asia Region

Introduction to ASEAN

Philippines

Brunei

PR of China

Day 4

India

Malaysia

Singapore

Hong Kong

Indonesia

Thailand

Vietnam / Cambodia / Laos

Day 5

Taiwan

Korea

Outline on Japan

Asean Harmonisation

Day 6

Module 3: Pharmaceutical Regulatory Affairs in Africa

Basic Terms & Environment

Harmonisation initiatives within Africa

Regional Presentations

Each regional presentation will cover:

- The development of drug control
  - The regulatory authorities
  - Other influences
- Regulatory submission strategy
  - How to determine an appropriate submission strategy
  - A practical approach
- The development of drug control
  - The regulatory authorities
  - Other influences
- Company and product registration
  - Regulations and guidelines
  - New products and line extensions
  - Labelling requirements
  - Registration samples and certification/legalisation
- Compilation of the dossiers
  - Contents and formats
  - Hints on success/failure
  - Specific country requirements
- Regulatory authority/agency assessment
  - Process
  - Timelines

South Africa

- Influences and changes
- The new SAHPRA guidelines
- Latest regulatory processes adopted by SAHPRA
- Complementary and alternative medicines status
- Marketing code for the advertising of medicines

Namibia

Botswana

Zimbabwe

Zambia

Day 7

Malawi

Tanzania

Kenya

Uganda

Nigeria

Ghana

Maghreb Countries - Algeria, Morocco, Tunisia

Day 8

Module 4: Pharmaceutical Regulatory Affairs in Latin America

Latin America regulatory environment: Legal Basis

Key Regulations, Directives and Guidelines

Impact and influence of the Main Regulatory Authorities in Latin America

- Argentina
- Brazil
- Chile
- Cuba
- Colombia
- Mexico

Harmonisation initiatives within Latin America

Adoption of the Common Technical Document

Drug Development: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- Regulatory Authorities
- Regulations and regulatory considerations

Marketing Authorisation: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- Regulations, requirements and regulatory intelligence-based strategy
- Registration and certification/legalisation samples

Compilation of Dossiers: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- Contents and formats
- Tips for success/failure
- Country specific requirements

Compilation of Dossiers: Argentina, Brazil, Chile, Cuba, Colombia & Mexico (continued)

- Regulatory authority/agency assessment
- Process
- Deadlines

Regulatory Submission Strategy: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- How to determine an appropriate submission strategy
- A practical approach

Commercial Structure: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- Registration of companies and products
- Regulation and guidelines

Day 9

Module 5: Pharmaceutical Regulatory Affairs in Russia and the Eurasian Union

CIS – Regional Regulatory Overview

- CIS and Russia Market Overview
  - Market protection policies
- CIS and Russia in regional and international Regulatory Harmonisation

Common Regional Requirements in CIS

- Administrative data, translations, normative document, samples, labelling, etc

Eurasian Economic Area

- Countries current members of EAEU and EAEU Official bodies
- History of EUAE, scope of products, available experience
- Terms of transition period for medicines

Eurasian Regulations for Medicines

- Overview of EAEU regulatory framework
- Registration Procedures and Application process
- EAEU submission documents and data requirements
- GMP inspections
- PhV requirements

Programme

Day 10

Registration of Medicine in Russia

- Regulatory authorities in Russia
- Key regulations governing registration process
- Clinical trials

National Regulatory Procedures in Russia

- Application dossier and data requirements
- Post approval life cycle maintenance applications
- Safety reporting and market surveillance
- Price and reimbursement
- Patent data protection

Registration in other EAEU countries

- Kazakhstan, Belarus, Armenia, Kirgizstan

Registration in other CIS countries

- EU sphere of influence: Ukraine, Moldova, Georgia
- National procedures: Azerbaijan, Uzbekistan, Tajikistan, Turkmenistan

Workshop – CIS Regional Regulatory Strategy

Day 11

Module 6: Pharmaceutical Regulatory Affairs in the Middle East

Introduction to Regulatory Affairs in the Middle East

General overview on the following topics:

- Markets and culture
- Healthcare
- Business culture
- Regulatory environment and characteristics
- General regulatory requirements
- Company and product registration
- Variations and renewals
- Pharmacovigilance
- Regulatory summary

Economic Overview of the Middle East

- Population and GDP per capita
- Unemployment rate
- GDP real growth rate
- Inflation rate
- Healthcare spend per capita

Saudi Arabia

Bahrain

Qatar

Oman

Kuwait

Yemen

UAE

Day 12

Egypt

Sudan

Libya

Syria

Lebanon

Jordan

Iran

Iraq

Palestine

Israel

Local Trade Associations

MERC

Day 13

Module 7: Pharmaceutical Regulatory Affairs in China

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 14

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

Norah Lightowler

Norah Lightowler is a partner in Lightowler Associates, an independent consultancy offering regulatory advice and support to pharmaceutical companies in or proposing to enter the European market for human pharmaceuticals. They are in their twenty fourth year of successful business. She has wide experience in the pharmaceutical and related nutraceutical, herbal and devices industries as a pharmaceutical assessor with the UK regulatory authority and as associate director of European regulatory affairs with an international pharmaceutical company. She is experienced in organising and presenting courses on European regulatory control systems, including requirements, procedures and strategy.

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*.

Salma Ismail

Salma Ismail is the CEO of Twinz Regulatory Affairs Pharmacist Consultants based in South Africa. Salma has over 25 years' experience in the Pharmaceutical Industry and in Regulatory Affairs, which includes understanding of legislation, technical issues, marketing regulations, training within the pharmaceutical industry and the submission of new chemical entity, generic, biological medicine and complementary medicines (including health supplements) applications as well as medical device applications to regulatory authorities within the SADC region. She is also involved in academia by lecturing on relevant pharmaceutical regulatory matters in prestigious universities in South Africa. Salma is the former Chairperson of SAPRAA (Southern African Pharmaceutical Regulatory Affairs Association).

Presenters

Makram Nehme

Makram Nehme is a Regional Regulatory Consultant having relevant experience with multiple multinationals including Parexel international, based in Lebanon. He has more than 10 years' experience in the Pharmaceutical and Medical Device Industry and is a Regulatory Expert covering the Middle East and North African markets. His experience includes negotiations with the Ministry of Health and Drug Agencies in the region, as well as training of key personnel and he has a proven record in regulatory submissions, analysis, product pricing and reimbursement across the MENA region.

Belkys Ruiz

Pharmaceutical Chemist graduated from Universidad Central de Venezuela, with more than 15 years of experience in the Pharmaceutical Industry and solid knowledge in the life cycle of medicines. Proficient in the different categories and types of products (new, innovative, generic and specific), medical devices, cosmetics including research, development, authorization and commercialization. I have a postgraduate degree in Drug Health Surveillance, and I play a strategic role in the area of regulatory affairs, leading teams and building links with the health authority in national and international companies in different countries (both Latin American and European region).

Anna Harrington-Morozova

Anna Harrington-Morozova is a regulatory, drug development and external relations professional with over 20 years' experience gained working in a Regulatory Authority, academia and industry. Anna graduated in Russia as a pharmacist. After working in the Russian Ministry of Health and the Clinical Pharmacology Department of Moscow Medical University, she held regulatory and external relation positions in the pharmaceutical industry and CROs in Russia and the UK, including senior regulatory affairs posts in GSK,EISAI, ICON and PRA. Anna currently acts a a Scientific and Reguatory director at Regem Consulting Ltd – a consultancy which focuses on drug development, global regulatory advice, professional trainings and flexible resourcing solutions for the pharmaceutical, biotech and medical device industries in emerging markets.

Ilona Putz

Ilona Putz is the founder and General Manager of PULONA Emerging Markets based in the UAE since 2008. Her company is dedicated to creating and developing tailor-made business concepts including regulatory consultancy for international manufacturers in the healthcare sector across the Middle East. Ilona has worked in the Pharmaceutical Industry since 1988 for companies like MSD, SmithKline Beecham, Karl Engelhard, HEXAL and Sandoz where she was the Regional Head, Middle East, for Sandoz International, Germany, responsible for all commercial and business development activities. She also consults for RegAff, Emergo and Dr. Regenold GmbH for the Middle East. Ilona spoke during the DIA Europe Meeting on "Clinical Trials in the Middle East" and at the Global Pharmaceutical Regulatory Affairs Summit 2021 and 2022. Moreover, Ilona published articles in the Journal of Medical Device Regulations on the regulatory overview for Medical Devices in Egypt, Kuwait and the UAE.

Heba Hashem

Heba has been working with Regulatory Affairs in the Middle East for more than 25 years. She has a Pharmaceutical and Business background being a graduate of the Faculty of Pharmacy (Cairo University), RAC certified in addition to an MBA at Maastricht School of Business. For the past 20 years Heba held the position of Middle East & Africa Regulatory and Quality Head at different Pharmaceutical and Medical Device companies; Gambro, Bayer and Novo Nordisk.

Heba is now the Middle East and Africa Associate Director at PPD where she is providing regulatory consulting services and training to Health Care companies.

Course date

10-14 June 2024,
17-19 June 2024,
24-27 June 2024 &
2-3 July 2024
(Non-consecutive days)

Live online
09:00-17:00 **UK (London)** (UTC+01)
Course code 15181

GBP **6,997.2**

How to book

Online:
ipi.academy/2723

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

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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