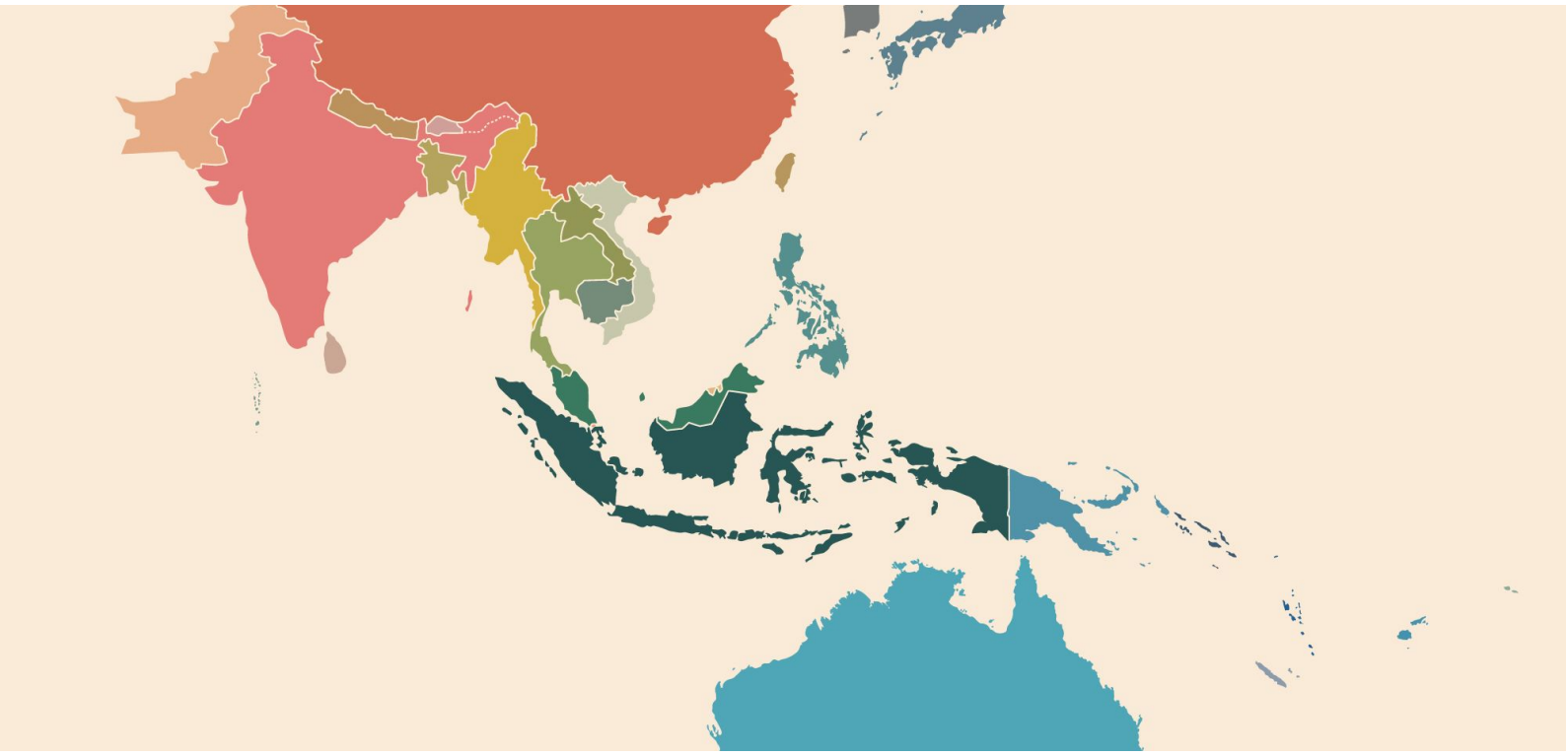
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Understanding Pharmacovigilance Regulations in APAC

8-9 July 2024
+ 8-9 October 2024

Pharmacovigilance regulations in Asia are dynamic and fast-changing. As the Asia-Pacific region becomes increasingly important for pharmaceutical companies, it's vital to ensure compliance and safety by staying informed of the latest regulatory developments.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Overview

Pharmacovigilance regulations in Asia are dynamic and fast-changing. As the Asia-Pacific region becomes increasingly important for pharmaceutical companies, it's vital to ensure compliance and safety by staying informed of the latest regulatory developments.

This two-day pharmacovigilance webinar has been designed to provide a comprehensive guide to compliance in this geographic region. It will provide an ideal opportunity to keep up-to-date with the latest Good Pharmacovigilance Practices (GVP) and post market PV operations in China, and post-market pharmacovigilance regulations in Singapore, Malaysia, the Philippines, and Australia.

Our panel of experts from this region will provide an overview of Good Pharmacovigilance Practices and discuss pharmacovigilance-related requirements. Gain key takeaways to better understand the new GVP regulations and pharmacovigilance compliance in these countries.

Don't miss this opportunity to learn from industry leaders and enhance your knowledge of dynamic and fast-changing regulations in Asia, and the growing market in the Asia-Pacific region.

Benefits of Attending

- **Gain** a comprehensive overview of Pharmacovigilance regulations in China, Singapore, Malaysia, the Philippines, and Australia
- **Stay updated** with the latest Pharmacovigilance regulations in these countries
- **Enhance** your Pharmacovigilance-related knowledge and skills
- **Understand** the local requirements for RPPV (QPPV), PSMF, RMP, and other related regulations in each of these countries

Who Should Attend

This webinar is intended for anyone involved in and interested in Good Pharmacovigilance Practices (GVP) and the daily practice of pharmacovigilance, including:

- Professionals working in pharmacovigilance departments
- Drug safety specialists
- Adverse reaction monitoring professionals
- R&D professionals
- Regulatory affairs specialists
- Pharmaceutical physicians

Programme

Day 1

Pharmacovigilance in China - GVP Overview

An Overview of China Pharmacovigilance

- Annual report of China national ADR monitoring
- China PV concept
- PV development in China
- Competent authorities
- National systems introduction

China GVP 2021 Introduction and Requirements

- Quality management: PV system, quality objective, QA system, QC indicators
- Organizational structure, personnel, resources: RPPV (QPPV), PV department
- Monitor and report: data collection, ICSR case processing, report submission, literature search
- Risk identification and evaluation: incl. PSUR/PBRER, post marketing safety study
- Risk control: risk control measures, risk communication, PV plan (RMP)
- Documentation, record and data management: incl. PSMF
- PV annual report
- Brief introduction of clinical PV requirements

Best Practices for Compliance with China's GVP Requirements

- 4 key tips
- 4 key pitfalls
- Authority inspection
- Q&A

Post-Market PV Operation

PV Operation - Individual Case Study Reports (ICSR)

- ICSR Overview
- Adverse Events Collection, Processing, and Submission to Regulatory Authorities
- National ADR Monitoring System Report Submission demonstration

Periodic Safety Update Report (PSUR)/PBRER

- Structures and contents
- Timelines

Day 2

Pharmacovigilance Regulations in Singapore, Malaysia, Philippines and Australia

Pharmacovigilance Regulations in Australia

- Introduction to Pharmacovigilance in Australia
- Pharmacovigilance system
  - QPPVA and Australian PV contact person
  - APSS (Australian Pharmacovigilance System Summary)
  - DAEN Database
- Reporting of Adverse Reactions
  - Timeframes, Reporting requirements.
- Significant safety issues
- Risk Management Plan (RMP) and Australia Specific Annex (ASA)
  - Submission requirements, Documents, Risk Minimisation activities
- Periodic Safety Update Reports (PSUR)
  - Reporting requirements, Format & contents
- Actions taken by other HA's.
- PV inspections and Pharmacovigilance inspection program (PVIP)

Pharmacovigilance Regulations in Malaysia

- Introduction to Pharmacovigilance in Malaysia and Legal Basis
- Pharmacovigilance system
  - Responsibilities of MAH, Responsible Person for PV (RPPV), Record Retention
- Managing ADR/AEFI reports
  - Collection, Validation of reports, ADR reporting systems, Timeframes, and Submission requirements
- Periodic Benefit-Risk Evaluation (PBRERs)
  - Overview, Format & content of PBRER, Submission requirements, Annexes
- Risk Management Plans (RMPs)
  - Objective, Structure, Submission requirements, Risk Minimisation activities
- Pharmacovigilance System Master File (PSMF)
  - Objective, Format & content of PSMF, Annexes
- Emerging Safety issues, Safety evaluation by NPRA, Safety communications
- Audits & Inspections

Pharmacovigilance Regulations in Singapore

- Introduction to Pharmacovigilance in Singapore and Legal Basis
- Responsibilities of the Company
- Adverse Event reporting
  - Reporting requirements, Records, Special situation reporting
- Risk Management Plans
  - Submission requirements, Documents, Risk Minimisation activities
- Periodic Benefit-Risk Evaluation (PBRERs)
  - Reporting requirements
- Actions taken by Regulatory Authorities

Pharmacovigilance Regulations in the Philippines

- Introduction to Pharmacovigilance in the Philippines and Legal Basis
- Pharmacovigilance system
  - QPPV
  - Records of PV
- Reporting of Adverse Reactions
  - Timeframes, Reporting requirements
- Significant safety Information
- Risk Management Plan (RMP)
  - Submission requirements, Documents, Risk Minimisation activities
- Periodic Benefit-Risk Evaluation (PBRERs)
  - Reporting requirements, Format & contents
- Actions taken by other national drug authorities
- PV inspections

Presenters

Raphael Tian

Pharmacovigilance Manager at Accestra Consulting

Mr. Raphael Tian is a seasoned pharmacovigilance Manager at Accestra Consulting, with extensive experience in top global pharmaceutical companies and a focus on the Chinese market. With hands-on experience in Adverse Event monitoring and reporting, Literature screening, Research Related Programs, Market Research and Patient Support Programs, PV agreements, Chinese GVP, and local regulations. Raphael is an experienced trainer in pharmacovigilance with a strong communication network in the local and global pharmaceutical industry in China. To learn more about Raphael or Accestra Consulting, please visit www.accestra.com.

Marylene Zhan

Senior consultant at Accestra Consulting

Ms. Marylene Zhan is a senior consultant at Accestra Consulting with extensive experience in pharmacovigilance and regulatory affairs, with a Master's Degree from the Zhongnan University of Economics and Law. Marylene is a seasoned bilingual and bicultural consultant who specialises in China regulatory compliance and pharmacovigilance services (RA/PV). She has a wealth of knowledge on Chinese Pharmaceutical regulations and in-depth insight into dealing with Chinese market access requirements. Marylene has a rich experience in serving international pharma companies with market entry into China, providing support in the areas of adverse event monitoring and reporting, literature screening, PV agreements, Chinese GVP and local regulations, SOP & PSMF writing, and more. To learn more about Marylene or Accestra Consulting, visit www.accestra.com.

Helen Ye

RA & PV Director at Accestra Consulting

- Ms. Ye has been dedicated to regulatory affairs consulting for 15 years with a Pharmacy degree from Zhejiang University, China.
- She is experienced in regulatory compliance of China market access & post-marketing maintenance of pharmaceutical products, providing insightful and customised solutions to international pharmaceutical companies and government institutions.
- She leads the registration team to plan, develop and implement compliance strategies for top pharma clients and has a successful track record for obtaining market approval for drug products, APIs, Excipients, Packaging Materials, medical devices and other products.
- Ms. Ye has a strong communication network with Chinese authorities (e.g. NMPA and CDE) and industry experts in China.
- To learn more about Helen or Accestra Consulting, please visit their website at www.accestra.com

Presenters

Param Dayal

Drug Safety Manager at Pharma To Market

Mr. Param Dayal is a qualified Microbiologist with Master's degree in Microbiology and a certified MedDRA coder. For the last 15 years, Param has worked on a variety of pharmacovigilance projects with special focus on ICSR processing (Unsolicited, solicited, Literature, legal and Clinical trials cases). In his previous roles he worked for organisations supporting pharma clients with PSP program management, PV audits, HA inspections, data migration, SOP Management, process refinement, providing PV training and mentoring to new staff. He also has experience working as a QPPV and Local Safety Officer for Australia and New Zealand. He is currently based in Melbourne working as Drug Safety Manager for Pharma To Market, managing PV activities for NZ clients.

Siew Man Phang

Ms. Siew Man Phang is a registered pharmacist in Malaysia, brings over 7 years of pharmacovigilance and regulatory expertise. She has served as QPPV for multinational pharmaceutical, generic, and distributor companies, gaining diverse experience across innovator drugs, generics, biologics, health supplements, traditional products, cosmetic and medical devices.

Additionally, she possesses extensive hands-on experience in pharmacovigilance, including adverse event monitoring & reporting, literature & regulatory Intelligence screening, risk management plan, SOP and PSMF writing. She is currently based in Malaysia, works as a Regulatory & Pharmacovigilance Assistant Manager in Pharma To Market handling various pharmaceutical clients, serving as QPPV and managing Pharmacovigilance activities in APAC regions.

Course dates

8-9 July 2024	**Live online** 09:30-12:30 **UK (London)** (UTC+01) *Course code 13850*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 03 Jun**
8-9 October 2024	**Live online** 09:30-12:30 **UK (London)** (UTC+01) *Course code 13993*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 03 Sep**

How to book

Online:
ipi.academy/2668

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
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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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