IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Understanding Pharmacovigilance Regulations in China

27 April 27
+ 11 October 27

A Practical Guide to China GVP Compliance, NMPA Requirements and Pharmacovigilance Audits.

Format:
Live online

CPD:
3 hours for your records

Certificate of completion

Course overview

China's pharmacovigilance (PV) regulatory landscape continues to evolve rapidly, making regulatory compliance increasingly important for pharmaceutical companies operating or planning to enter the Chinese market.

This comprehensive half-day webinar provides an up-to-date overview of China Good Pharmacovigilance Practice (GVP) requirements, post-marketing pharmacovigilance operations, and regulatory expectations from the National Medical Products Administration (NMPA). Participants will gain practical insights into implementing compliant pharmacovigilance systems while understanding how Chinese regulatory requirements align with global pharmacovigilance standards.

Led by experienced pharmacovigilance experts with extensive hands-on experience in China, the programme covers the complete lifecycle of local PV compliance, including GVP requirements, post-marketing safety activities, regulatory inspections, and GCP/GVP audits.

Whether you are responsible for global pharmacovigilance, local affiliate compliance, or vendor oversight, this webinar will help you better understand China's regulatory expectations, avoid common compliance pitfalls, and strengthen your pharmacovigilance quality system.

Join us to stay ahead of the latest developments in China's pharmacovigilance regulations and confidently manage compliance within one of the world's largest pharmaceutical markets.

Benefits of attending

By attending this webinar, you will:

- **Gain** a comprehensive understanding of China's pharmacovigilance regulatory framework and current GVP requirements
- **Stay** up to date with the latest developments in China Pharmacovigilance and NMPA expectations
- **Understand** how to establish and maintain a compliant pharmacovigilance system in China
- **Learn** the local regulatory requirements for:
  - Responsible Person for Pharmacovigilance (RPPV)
  - Pharmacovigilance System Master File (PSMF)
  - Risk Management Plan (RMP)
  - Aggregate Safety Reports (PSUR/PBRER)
  - Individual Case Safety Reports (ICSRs)
- **Understand** how GVP inspections are conducted by Chinese regulatory authorities
- **Learn** practical approaches to planning, conducting, and preparing for GVP audits of local partners and service providers
- **Identify** common compliance challenges and best practices for successful inspections

Who should attend

This webinar is designed for professionals involved in pharmacovigilance, drug safety, regulatory compliance, quality management, and GVP inspections and audits in China.

It is particularly relevant for:

- Pharmacovigilance professionals
- Drug Safety Specialists
- Pharmacovigilance Managers
- Medical Safety Scientists
- Adverse Event Case Processing Teams
- Regulatory Affairs Professionals
- Quality Assurance and GxP Auditors
- Clinical Safety Professionals
- Pharmaceutical Physicians
- Global PV and Local Affiliate Managers

Programme

An overview of pharmacovigilance in China

- 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
- Organisational 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

- Four key tips
- Four key pitfalls
- Authority inspection
- Q&A session

PV operation - Individual Case Safety Reports (ICSR)

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

Aggregate reports

- Structures and contents
- Timelines

Signals and risk management

- Signal detection and management
- Risk management activities

China GVP audit

- General audit scope
- Audit workflow
- Inspection readiness

Presenters

Marylène Zhan

Founder of PV Solutions Limited

Ms. Marylène Zhan has over 10 years of experience in pharmacovigilance (PV) and regulatory affairs (RA), with extensive expertise in supporting international pharmaceutical companies entering and operating in the Chinese market. She holds a Master's degree from Zhongnan University of Economics and Law.

As a bilingual and bicultural regulatory consultant, Marylène specialises in China regulatory compliance and pharmacovigilance services. She possesses in-depth knowledge of China's pharmaceutical regulatory framework and extensive experience navigating complex market access and compliance requirements.

Throughout her career, Marylène has successfully supported multinational pharmaceutical and biotechnology companies in achieving regulatory compliance in China. Her areas of expertise include GCP and GVP audits, Chinese GVP implementation and compliance, pharmacovigilance system establishment and optimisation, SOP development and quality management systems, regulatory intelligence, inspection readiness, and strategic regulatory consulting. She is committed to helping global organisations build compliant, efficient, and sustainable pharmacovigilance systems that meet China's evolving regulatory expectations.

Sherley Wang

Dr. Sherley Wang has over 16 years of experience in the pharmaceutical industry, including 11 years in pharmacovigilance and 5 years in clinical quality assurance. She has worked with leading multinational pharmaceutical companies and completed over 200 audits of hospital research centers and 150 audits of CROs and pharma companies. She is also an authorised RPPV/QPPV for several domestic pharma companies.

She authored the China Pharmacovigilance Industry Research Report 2024 and contributed to the translation of key pharmacovigilance books in collaboration with the CDE of NMPA. Sherley is a panel expert at the China Food and Drug Industries Quality and Safety Promotion Association (FDSA). She also teaches pharmacovigilance to graduate students at Tongji Medical College, Huazhong University of Science and Technology. She published a research report titled "2024 China Pharmacovigilance Industry Research Report", which received widespread attention in the industry.

As a member of the China Institute of Internal Audit (CIIA), Sherley is well-versed in GCP, GLP, GVP, and supplier audits, as well as regulatory inspections. She has deep knowledge of both domestic and international regulatory environments. Her experience enables her to support the setup and oversight of compliant PV systems for pharma companies.

Course dates

27 April 27	**Live online** 09:30-12:30 **UK (London)** (UTC+01) *Course code 17631*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 02 Mar**
11 October 27	**Live online** 09:30-12:30 **UK (London)** (UTC+01) *Course code 17632*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 16 Aug**

How to book

Online:
ipi.academy/3432

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

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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

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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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