BAIPHARM
Your Pharma Regulatory Partner

BAIPHARM

CONSULTING COMPANY

Our Team

BaiPharm Consulting is a professional service supplier for regulatory affairs in the pharmaceutical, medical device and food industry in China.

Believing in going the "extra mile" and always in pursuit of excellence, we deliver optimized solutions in compliance with China regulatory context, particularly with NMPA (formerly CFDA) regulations.

- A diverse team with strong background in multiple professional areas, incl. pharmacovigilance, regulatory compliance, pharmacy, toxicology, chemistry, etc.
- Global clients from 23+ countries & 100+ successful NMPA regulatory cases
- Headquartered in Hangzhou, with offices in Shanghai and Beijing.
- Extensive network of professionals

Our Strengths

15+ Years of Experience

In consultation of:

✓ Pharmacovigilance
✓ Regulatory compliance
✓ GMP compliance
✓ Registration for Medicine, Medical Devices and Food in China

Abundant Local Resources

✓ Close connections with local authorities
✓ Prompt info updates & communication
✓ Contracted laboratories
✓ Local Expert team and extensive professional network

Effective & Customized Solutions

✓ Quick response
✓ Quick grasp of your needs
✓ Optimized solution & workplan
✓ Aim for more values & reducing risks

Specialize in Serving International Clients

✓ Global vision
✓ Rich experience with 23+ international clients
✓ Cross-cultural communication
✓ Streamlined project management

Our Partners & Clients

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CHINA PHARMACOVIGILANCE (PV)

Good Pharmacovigilance Practices (GVP) 2021 was officially released in May 2021 and entered into force since December 1st, 2021, opening a new chapter for Pharmacovigilance in China.

COMPETENT AUTHORITY

- Center for Drug Evaluation of NMPA (CDE) → For Clinical PV
- Center for Drug Reevaluation of NMPA(CDR) / National Center for ADR Monitoring → For Post Marketing PV

POST MARKETING PV

Quality Management System



Monitor and Report
(Individual Case Safety Report) ICSR

Four elements:
1. Identifiable patients
2. Identifiable reporters
3. Suspected drugs
4. ADR details

1. Timeline: non-serious ADR shall be reported within 30 days and serious ADR ASAP (within 15 days) from the date of first case found by MAH.
2. ADR from literatures: submit as ICSR if suspected drug is holding by MAH; include in PSUR with analysis if not sure it is MAH's drug.
3. Serious ADRs abroad: submit as ICSR.
4. Cases from relevant studies or data collection programs which is related with suspected drug: submit as ICSRs.

Literature Screening

Frequency

1. New drug first-marketed globally or first imported to China within 5 years: once every two weeks
2. Others: once a month

Database Requirements

Two English databases
Two Chinese databases

Literature Screening

Period

Continuous screening, no gaps

Database Examples

Chinese: CNKI, VIP, Wanfang
Global: PubMed, Embase, Ovid

PSUR (Periodic Safety Update Report)

Reporting period: complete and continuous; start from CBD/IBD

- Innovative/improved new drug: every year within first 5 years, then once every 5 years after license renewal;
- Others: every 5 years

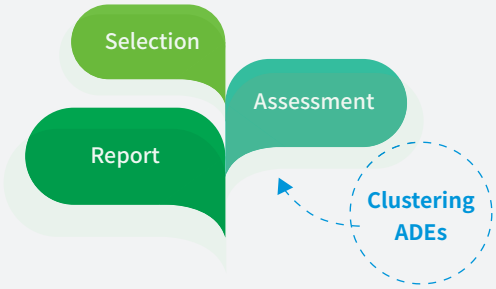
Reviewed and approved by RPPV/QPPV

Can be replaced with PBRER

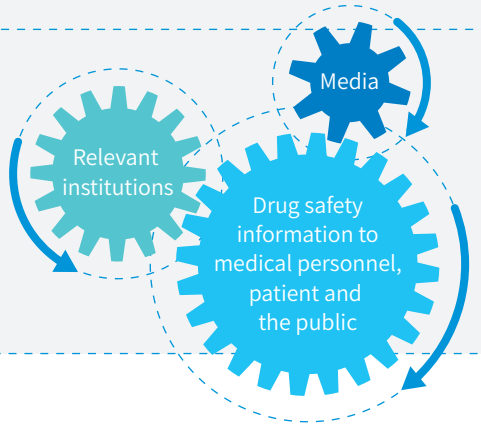
Exemption: API, in-vitro diagnostic reagent, Chinese medicinal materials and decoction pieces

RISK CONTROL

Risk Control Measures



Risk Communication



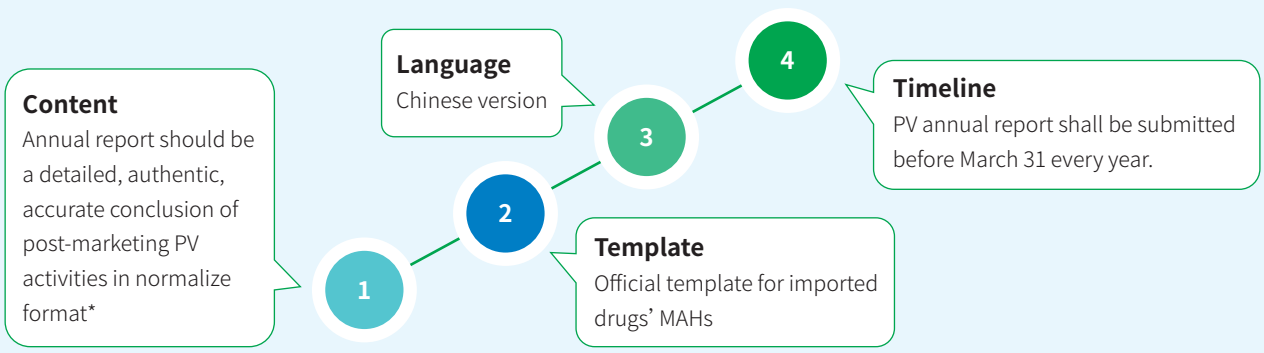
Pharmacovigilance Plan

Pharmacovigilance Plan (PV Plan) is the documentation describing marketed drug's safety features and how to manage drug safety and risk, which is part of RMP.	**Definition**
Create PV Plan for marketed drugs with identified significant risks according to the risk assessment result, and update it timely.	**Design**
PV Plan includes drug safety overview, PV activities, designed risk control measures, implementation timeline, etc.	**Content**
PV Plan shall be reviewed and approved by internal Drug Safety Committee.	**Review**

PSMF

· Organization: PV related organizational structure, duties and relationships, etc.
· RPPV/QPPV's basic information incl. residency region, contact info, CV, duties, etc.
· Specialized personnel status, incl. quantity, relevant background, duties, etc.
· Sources of suspected ADR, incl. main collection channels, methods, etc.
· Information tool/system introduction
· Management policy and SOP
· Pharmacovigilance system operation description
· PV entrustment introduction
· Quality management
· Annexes incl. system and SOP, drug list, entrustment agreements, internal audit reports, PSMF modification log, etc.

PHARMACOVIGILANCE ANNUAL REPORT



* incl. pharmacovigilance system development, individual ADR collection and reporting, monitoring data regular analysis and evaluation, risk assessment and control, etc.

CLINICAL PV

SUSAR	DSUR
• Shall submit via gateway in E2B (R3) format • Fatal or life-threatening: report ASAP within 7 days once found and submit follow-up report within 8 days after first reporting • Others: report ASAP within 15 days once found and submit follow-up report within 15 days after receiving new information	• Starting date: DIBD • Timeline: First DSUR shall be submitted within 2 months since first IBD after CTA approved in China.

OUR SERVICE

• Case (ICSR) Reporting: Processing, QC and Submission of Post-marketing Individual Case Safety Reports
• Literature Screening
• Signal Monitor and Risk Assessment
• China RPPV/QPPV Support (Responsible Person for Pharmacovigilance)
• Periodic Safety Update Report (PSUR)
• China Risk Management Plan (RMP)/Pharmacovigilance Plan
• PV Annual Report
• PV System Master Files (PSMF)
• Competent Authority Audit Support
• Team training, Business partners overview
• SUSAR and DSUR (for Clinical PV)