ABOUT US

iPharmX is a Singapore registered pharmaceutical service partner providing expert Pharmacovigilance, Medical Information, Clinical Operations, Regulatory Services and Data Management support. We enable compliant, efficient and patient focused solutions across clinical development and post-marketing activities

Operating across **Singapore, Malaysia, South Korea, Taiwan, Hong Kong, Brunei, Vietnam, China, Indonesia, Thailand and India**.

iPharmX delivers scalable and customized regional support aligned with client objectives and country specific regulatory compliance requirements

OUR SERVICES

- Pharmacovigilance
- Medical Information
- Clinical Operations
- Regulatory Services
- Data Management

Partner with Us

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Follow us :

iPharmX

Compilance ● Quality ● Regional Expertise

EXCELLENCE

in Pharmaceutical Services

We Support APAC & Beyond

Why Choose iPharmX

- A dedicated team of experienced professionals with a strong track record in supporting global pharmaceutical clients with Big Pharma and CRO Backgrounds
- Robust Quality Management System (QMS) and SOP framework in adherence with local and global regulatory requirements
- Cloud based Secure IT (Cloud PC, Microsoft 365, Bitdefender, 2FA), GDPR/PDPA compliance and Business Continuity/Disaster Recovery are in place
- Flexible engagement models tailored to client needs and strategic consulting
- Bridges diverse regulatory frameworks, local language and cultural nuances across APAC
- Local expertise to enable successful implementation of projects seamlessly.

PHARMACOVIGILANCE SERVICES

- Qualified Person for Pharmacovigilance (QPPV) / Local Safety Officer (LSO) Services
- Pharmacovigilance system setup & maintenance
- Compliance with global (FDA guidelines, International Council for Harmonisation (ICH-GCP) and local regulatory requirements
- End-to-end case processing & reporting (ICSRs, PBRER,PSUR,DSUR, RMPs)
- Signal detection & Risk management
- Additional Risk Minimization Measures (aRMMs) Preparation
- Literature screening & Analysis
- Organized data collections program Safety consultation (Patient Support Programs, Market Research & Digital assets etc)
- PV training & SOP development
- Post-Marketing Surveillance (PMS)
- Pharmacovigilance System Master File (PSMF) preparation & maintenance
- Safety Data Exchange Agreements (SDEA) preparation
- Pharmacovigilance audits & inspections Support

QUALIFIED DATA MANAGEMENT SERVICES

- Database design, build, and maintenance in EDC systems (Medidata Rave/Zelta), including CRFs, edit checks, coding, RTSM setup, and CDASH-compliant updates.
- Study start-up support: Data Management Plan (DMP), data transfer specifications, eCRF guidelines, and site training materials.
- Study conduct activities: Data cleaning and validation, query management, SAE and lab reconciliation, external data reconciliation, protocol deviation tracking, and EDC user management.
- Study close-out: Final data cleaning, query resolution, database freeze/lock, and archival.
- Trial Management File (TMF) documentation and inspection readiness support.

REGULATORY SERVICES

- Regulatory Strategy, Intelligence and Technical Advisory
- Dossier Development and Regulatory Submissions (NDA and lifecycle filings)
- Health Authority Engagement and Query Management
- Product Lifecycle and Post Approval Management
- Compliance, Promotional Review and Regulatory Systems Support

CLINICAL OPERATIONS

- Clinical trial regulatory and submission support
- IIT and Real-World Evidence (RWE) study management
- Site and vendor coordination
- Study documentation and TMF oversight
- Operational compliance and quality oversight

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Compliance ● Quality ● Regional Expertise

MEDICAL INFORMATION SERVICES

- Medical query management and scientifically balanced response handling
- Literature review and evidence-based research support
- Development and maintenance of Local Standard Response Documents (LSRDs)
- Mailbox management, triage and safety escalation
- Local adaptation and medical review of global materials
- Scientific content compliance and promotional review support