

# Pharmacovigilance Services



## Aims and Objectives

We aim to provide comprehensive pre approval and post marketing safety surveillance and risk management services at world class quality and low costs.

At GVK BIO, we believe in fostering long-term relationships with our clients. We understand and respect the service imperatives and aim to satisfy commitments, in terms of quality, budget and timeliness, and meet client's requirements at all levels of operation.

We strive to help clients maintain the highest standards in pharmacovigilance operations, thereby reducing the risk of post marketing drug withdrawal or other statutory actions.

## Business Models

Agile and flexible business models.

- End to end solutions for all pharmacovigilance needs of your organization.
- Customized solutions to suit your specific needs.

## Key Advantages

- Integrated end to end and customized solutions for meeting client requirements.
- SOP driven processes with stringent quality control.
- Cost effective services.
- Trained staff comprising of healthcare professionals and Pharmacovigilance specialists.
- Scalability to multi-linguistic skills and multiple locations.

## Talent

Trained manpower with experience in successfully handling pharmacovigilance inspections by authorities such as USFDA, MHRA, and Health Canada.

Comprehensive knowledge of the stringent worldwide regulations helps us meet global pharmacovigilance requirements.

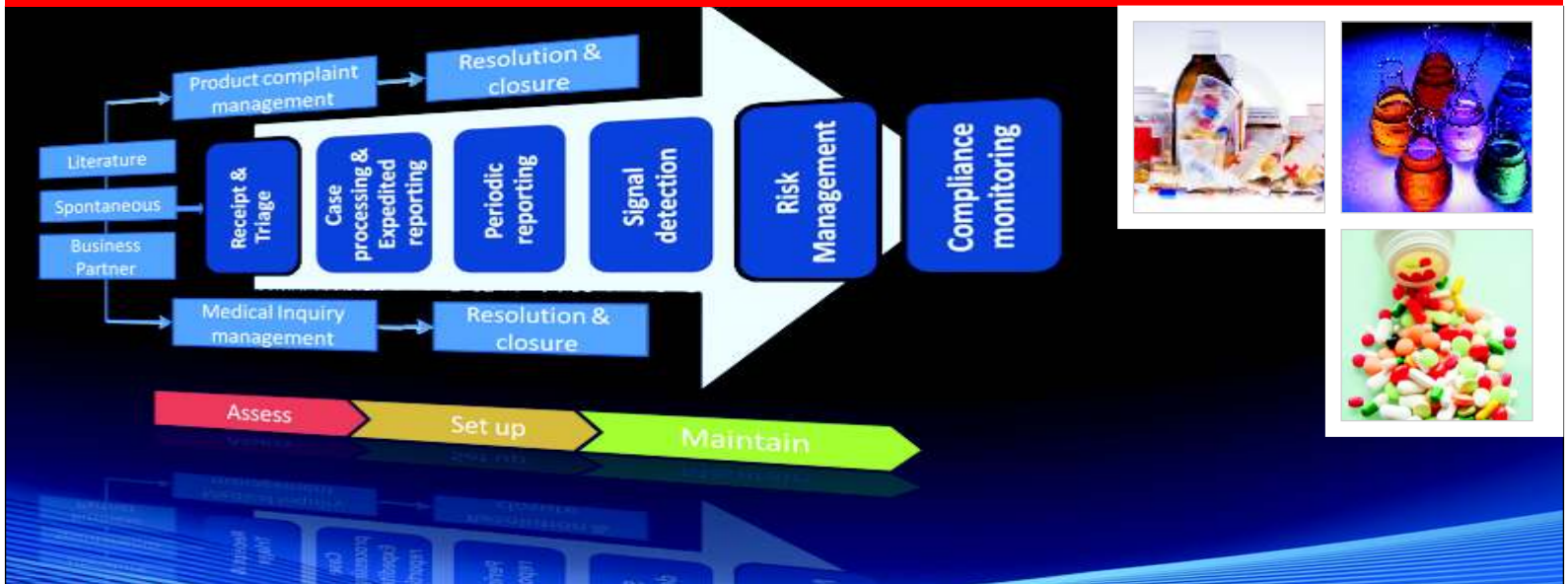
## About GVK BIO

GVK Biosciences, India's premier Contract Research Organization, delivers integrated research services. The company accelerates the Drug Discovery and Development process of its customers through science and innovation.

Informatics | Medicinal Chemistry | Biology  
Process R&D and Custom Synthesis | Clinical Research | Clinical Pharmacology

**GVK**BIO  
Accelerating Research

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## POST-MARKETING PHARMACOVIGILANCE

1. **24x7 Customer Call receipt & Triage**
  - Call receipt 24X7
  - Call triage & routing to appropriate stakeholder
  - Call information capture in database
  - Forward integration with case processing services
2. **ADR case processing & reporting**
  - Data entry into validated electronic database including historic safety data
  - Quality control
  - Medical review, narrative writing, MedDRA coding
  - Reporting: Electronic (E2B), Hard copy (CIOMS, MedWatch 3500A drug, etc.)
3. **Periodic ADR Reporting (PSURs)**
  - Complete PSUR generation
  - Formats: ICH E2C, Volume 9a, US FDA CFR Part 314.80, Schedule Y
  - Literature searches
  - Generation of case narratives
4. **Product Quality Complaints (PQC) Management**
  - Call receipt 24X7
  - Management of complete cycle from receipt of complaints to response to complainants
  - Complaint processing into database
  - Complaint distribution to Quality Assurance locations and follow up for analysis report
  - PQC reconciliation
  - Medical analysis of complaints
5. **Medical Inquiries Management**
  - Call receipt 24X7
  - Management of standard and off label customer inquiries
  - Management of complete cycle from receipt of inquiries to response
  - Capture of inquiries in database
6. **Electronic Safety Database Validation**
  - Validation plan preparation
  - End to end validation activities
  - Post 'Go live' support
7. **Safety Data Exchange Agreement Management**
  - Drafting SDEAs customized per global regulatory requirements
  - Review of SDEAs
  - Exchange of ADRs with business partners after execution of SDEAs

8. **Signal Detection- Benefit Risk Evaluation**
  - Causality and Medical assessment, statistical analysis.
9. **Risk Management Plans/Programs**
  - Writing Risk Management Plans as defined in the Template for EU RMP
10. **Literature monitoring for ADRs, Full text articles**
  - Ongoing, weekly literature monitoring for identification of ICSRs (Individual Case Safety Reports)
  - Active ingredient specific - alternative names/ Product specific
  - Integration with case processing in safety database
  - Full text articles procurement
11. **Training of company employees on ADR reporting**
  - Pharmacovigilance specific trainings for pharmacovigilance department
  - Training on pharmacovigilance for company employees including medical representatives
12. **Global Compliance monitoring and audits**
  - Review of company's compliance data on monthly basis
  - Pharmacovigilance audits and recommendations
13. **Inspections Management**
  - Support for management of inspections by global regulatory authorities
  - Support for CAPA execution for closure of inspection findings
14. **Department restructuring, turnkey operation**
  - SOP development
  - Recommendations for pharmacovigilance department designing and development
  - Recommendations for improvements in the existing pharmacovigilance systems

## PRE- AUTHORIZATION PHARMACOVIGILANCE

15. **End-to-End SAE Management Services**
  - 24 x 7 Call Receipt & Triage
  - Processing of SAEs & Electronic Reporting
  - Causality Assessment
  - Annual Safety Reports
  - Clinical Trials Safety Data Management

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