



EasternPharma  
Endless Possibilities



**Pharmacovigilance**

**Elevating  
Excellence in  
Product Safety**

**Safety is a choice, not a chance.**  
Choose Pharmacovigilance today and secure your business future.

# Is Your Therapeutic Product Safety Assured?

**Pharmacovigilance:** Are you fulfilling your responsibilities as a sponsor of therapeutic products?

Being a sponsor of therapeutic products necessitates rigorous adherence to the TGA's post-market reviews and audits. Compliance with both pre and post-market responsibilities is crucial to maintain your product's standing on the Australian Register of Therapeutic Goods (ARTG).

Do you have:

- Ongoing Stability Data that validate your product's shelf life, storage conditions, and expiration date?
- A Comprehensive Pharmacovigilance (PV) System in place, aligned with the TGA's Pharmacovigilance Inspection Program, for monitoring and reporting adverse events and significant safety issues?
- A program for monitoring and updating against industry regulatory amendments?

**Ensure your business is prepared and safeguarded.**

**Don't risk your product's standing or, more importantly, consumer safety.**

## Our Solution - Your Assurance

**Our services are designed to provide comprehensive support for your pharmacovigilance needs. We offer three distinct solutions:**

- **1. TGA-Compliant Pharmacovigilance Program:**

We have developed a robust system, grounded on the TGA's pharmacovigilance guidelines, audit outcomes, and supplemented with EMA Pharmacovigilance Guidelines where necessary. This all-encompassing program readies you for a successful TGA audit and ensures your ongoing compliance.

- **2. Annual Pharmacovigilance Management:**

We provide a year-round management service to help you stay on top of pharmacovigilance activities. Our dedicated team will monitor and report adverse events, manage your pharmacovigilance data, update your procedures in line with regulatory amendments, and ensure all your pharmacovigilance responsibilities are met throughout the year.

- **3. Online Training Course:**

In addition to our system and management services, we offer a comprehensive online training program for sponsors and pharmacovigilance staff. This flexible, accessible course equips you with the latest knowledge on pharmacovigilance practices and updates you on any changes in regulations.

Our trio of solutions gives you the assurance of complete pharmacovigilance compliance, keeping you aligned with both local and international standards. Choose the solution that fits your needs, or combine them for a fully integrated approach to pharmacovigilance.

**Safety is a choice,  
not a chance.**  
Choose Pharmacovigilance  
today and secure your business future.

**EasternPharma**  
Endless Possibilities



## **The Components of our Comprehensive Pharmacovigilance Program**

**The Components of our Comprehensive Pharmacovigilance Program  
Our system is composed of 20 detailed documents, including:**

- 1-SOP Pharmacovigilance for Complementary Medicines
- 2-Pharmacovigilance Glossary
- 3-Pharmacovigilance Contact Person Checklist Master
- 4-Pharmacovigilance Training Log
- 5-Adverse Event Checklist Master
- 6-Adverse Event Report Master
- 7-Adverse Reaction Checklist Master
- 8-Adverse Reaction Report Master
- 9-Adverse Reaction Monitoring Log Master
- 10-Significant Safety Issue Checklist Master
- 11-Significant Safety Issue Report Master
- 12-Recall Assessment Form Master
- 13-Recall Checklist Master
- 14-Incident Detection Master
- 15-Medicine Defect Checklist Master
- 16-Medicine Defect Report Master
- 17-Overseas Manufacturer Partner Obligation Checklist Master
- 18-Overseas Manufacturer Partner list Master

**Any updates that emerge from audits will be provided at no extra charge. Training materials will also be given for future staff training.**





## Why Choose Our Pharmacovigilance System?

- **Elevated Standards:** Our program goes beyond just meeting minimum requirements, setting a new benchmark in consumer safety and therapeutic product efficacy.
- **Comprehensive Approach:** We fulfill not only the "musts" but also the "shoulds" that TGA inspections identify as significant, while meeting global pharmacovigilance standards.
- **Global Best Practices:** Our program, while strictly adhering to TGA's standards, integrates global best practices in pharmacovigilance, ensuring alignment with both local and international regulations.
- **Ongoing Monitoring:** We continuously monitor audit feedback and regulatory updates globally, keeping your system at the forefront of safety and compliance.
- **Partnership:** Choosing our program means choosing a partner invested in your success, a partner committed to aligning your business with safety and legislative priorities worldwide.
- **Peace of Mind:** Our program brings confidence in your compliance practices and safety measures, offering peace of mind in a world of ever-changing regulations.
- **Competitive Pricing:** Our program is competitively priced, providing a balance between cost-effectiveness and superior service delivery.

Reach out to us today to make the right choice for your business. Your commitment to global safety and quality starts here.

