Global Pharmacovigilance Strategy, Safety Governance & Compliance

US • EU • UK • APAC

For Pharma & Biotech Companies, CROs, Consulting firms

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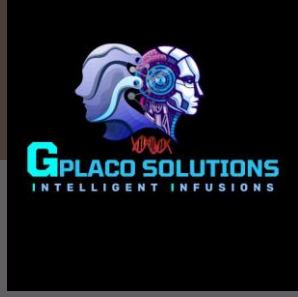

Executive Leadership Session:

This executive-level session focuses on the design and implementation of a global Pharmacovigilance strategy across the US, EU, UK, and APAC, with emphasis on governance, risk-based oversight, compliance, and inspection readiness.

The program is intended for senior leadership involved in safety, quality, risk, and regulatory decision-making.

Global Training Schedule:
US|EU|UK| APAC

On January 21, 2026:

- UK: 3:00 – 5:00 PM
- EU (CET): 4:00 – 6:00 PM
- US East (ET): 10:00 AM – 12:00 PM
- US Central (CT): 9:00 – 11:00 AM
- US Pacific (PT): 7:00 – 9:00 AM
- India (IST): 7:30 – 9:30 PM

For enquiries and advance fee payment to secure your seat, please write to:

contactus@globalplacosolutions.com

Last date to Register – January 10, 2026

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Optimized for Executive & Leadership Participation

Session Design

- **2-hour executive-focused session**
- **Strategy-led (not operational training)**
- **Live interaction + Q&A**
- **Post-session access to executive-level strategy frameworks, templates, and implementation roadmaps**
- **Includes 2 hours of complimentary consulting & advisory on Global PV Strategy and Safety Governance.**

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Why a Global PV Strategy is Critical?

- Increasing regulatory scrutiny (FDA, EMA, MHRA, PMDA)
- Complex global regulations & partnerships
- High-risk therapies and accelerated approvals
- Expectation of proactive risk management

Who should attend?

- Chief Risk Officer (CRO)
- Chief Quality Officer / Head of Quality
- SVP / VP Pharmacovigilance or Drug Safety
- Global QPPV / EU QPPV /UK QPPV
- US, EU and UK Head of Safety

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Global PV Strategy Framework

- Unified global governance model
- Risk-based operations & oversight
- Harmonized processes across regions
- Technology-enabled compliance

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Safety Governance Model

- Global QPPV & regional safety leadership
- Safety committees & escalation pathways
- Clear RACI and accountability
- Management oversight & decision logs

SDEAs / PVAs Governance

- Implementation and execution of SDEAs/PVAs
- Clear delegation of safety responsibilities
- Oversight clauses and KPIs
- Audits and compliance monitoring
- Change management & termination clauses

ICSR Management

- Global Case management & Workflow
- Case receipt, processing and monitoring
- Expedited reporting compliance
- Medical review and QC/QR
- Global Reconciliation
- Safety database & Maintenance

Literature Surveillance

- Global and local Literature workflow
- Literature search and review strategy
- Implementation of global Reconciliation
- Automation and AI-enabled screening

Benefit-Risk Evaluation

- Continuous benefit-risk monitoring
- Methodologies, scheduling
- Global preparation & Submissions
- Cross-functional safety assessments
- Regulatory communication strategies

Signal Detection & Management

- Global Signal Management & Workflow
- Statistical and clinical signal detection
- Governance of signal review committees
- Documentation and traceability
- Health authority interactions

RMP/REMS Strategy

- EU RMP vs US REMS alignment
- Risk evaluation and minimization measures
- Pharmacovigilance plan execution
- Effectiveness assessment
- Global submissions and compliance

Global & Local PSMF

- Global PSMF with annexes
- Registration & Maintenance
- US safety system alignment
- Inspection-ready documentation

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QA & Compliance Oversight

- Risk-based audit programs
- Audit Plan & Strategy
- CAPA lifecycle management
- Partners audits– affiliate, License Partners, and Distributors
- Vendors audits – CROs, Service providers

Technology & Digital PV

- Global safety database
- System validation (21 CFR Part 11 / Annex 11)
- Data integration (EDC, CTMS)
- Analytics & dashboards

Outcome & Value ?

Gains of the training program

Design strategy before operations scale – US/EU/UK

- >95% data quality
- No missed cases or late submissions
- Proactive Signal detection
- Risk minimization & effectiveness
- Zero critical findings in inspections
- 100% regulatory compliance
- Fully automated AI/ML processes
- Accelerate approvals & commercialization

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GPLACO SOLUTIONS

– The global PV experts & Your Strategic Partner

- Global PV strategy & Safety governance
- PVQA & compliance
- Vendor oversight & audits
- AI-enabled PV transformation

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