Advanced Good Pharmacovigilance Practices (GVP) Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The pharmaceutical landscape is undergoing a rapid digital transformation, driven by evolving global regulatory standards and the integration of sophisticated technologies like Artificial Intelligence (AI) and Real-World Evidence (RWE). This necessitates a fundamental shift from reactive case-processing to proactive safety surveillance and benefit-risk optimization. Advanced Good Pharmacovigilance Practices (GVP) Training Course is meticulously designed to equip experienced professionals with the mastery required to navigate these complexities. This program goes beyond the core GVP fundamentals, delivering in-depth, practical expertise in Signal Management, advanced Risk Management Plan (RMP) development, Pharmacovigilance System Master File (PSMF) maintenance, and inspection readiness. Key skills cultivated include data-driven decision-making and the strategic implementation of a Quality Management System (QMS) within the pharmacovigilance framework, ensuring global compliance and enhancing patient safety.

To maintain competitive advantage and uphold the highest standards of patient safety, organizations must invest in personnel who are proficient in the next-generation pharmacovigilance framework. This advanced course provides the strategic insight and technical competencies to lead a robust and future-proof PV department. Participants will gain practical knowledge in handling complex global reporting obligations, leveraging pharmacovigilance analytics for early signal detection, and implementing effective risk minimization measures (RMMs). The curriculum?ÇÖs focus on ICH guidelines (E2 series), Due Diligence for product acquisitions, and proactive crisis management ensures graduates can immediately contribute to operational efficiency, regulatory excellence, and the preservation of a product's positive benefit-risk profile.

Programme Curriculum

Advanced Good Pharmacovigilance Practices (GVP) Training Course

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Course Duration

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Course Objectives

1. Master the application of the latest EU GVP modules and ICH E2 series guidelines for global regulatory compliance.
2. Develop and maintain a fully Inspection-Ready Pharmacovigilance System Master File
3. Implement advanced signal detection methodologies, including the use of pharmacovigilance analytics and data mining.
4. Design, execute, and evaluate the effectiveness of risk minimization measures
5. Conduct comprehensive Benefit-Risk Assessments throughout the product lifecycle.
6. Lead and manage Pharmacovigilance Audits and Inspections, including for-cause and remote inspections.
7. Integrate Real-World Evidence (RWE) and Real-World Data (RWD) into safety surveillance processes.
8. Formulate and update robust Risk Management Plans (RMPs) in line with EU and global requirements.
9. Optimize Individual Case Safety Report (ICSR) processing using automation and AI in pharmacovigilance.
10. Prepare and critically evaluate Periodic Benefit-Risk Evaluation Reports (PBRERs/PSURs) and DSURs.
11. Establish and maintain a robust Pharmacovigilance Quality Management System (QMS) for continuous improvement.
12. Navigate the complexities of Pharmacovigilance in Clinical Trials and the new EU Clinical Trial Regulation (CTR).
13. Apply due diligence principles for licensing agreements and product acquisitions from a PV perspective.

Target Audience

1. Pharmacovigilance (PV) Managers and Directors
2. Qualified Person for Pharmacovigilance (QPPV) and Deputy QPPVs
3. Safety Scientists and Signal Management Specialists
4. Regulatory Affairs Professionals focused on safety submissions
5. PV Quality Assurance (QA) and Audit Specialists
6. Drug Safety Physicians and Medical Directors
7. Clinical Research Professionals with PV responsibilities
8. Personnel involved in licensing, acquisitions, and due diligence teams

Course Modules

1. Advanced EU GVP and Global Regulatory Framework

- Deep dive into GVP Modules I & II
- Understanding the role of EMA, PRAC, and national competent authorities.
- ICH E2 series principles (E2C(R2), E2D, E2F) and their application.
- The impact of the new EU Clinical Trial Regulation (CTR) on PV.
- Case Study: Analyzing a major regulatory non-compliance penalty due to failure in implementing GVP Module I-compliant QMS.

2. The Pharmacovigilance System Master File (PSMF)

- Detailed review of PSMF content, structure, and Annexes.
- Best practices for continuous PSMF maintenance and version control.
- The PSMF as a central tool for inspection readiness.
- Management of outsourced PV activities and inclusion in the PSMF.
- Case Study: Drafting a strategy for merging two separate PSMFs following a pharmaceutical company acquisition.

3. Advanced Individual Case Safety Report (ICSR) Management

- Complex causality assessment and MedDRA coding principles.
- Expedited reporting requirements across multiple jurisdictions
- Managing special situations.
- Leveraging AI and Natural Language Processing (NLP) for automated case intake and triage.
- Case Study: Applying advanced causality assessment to a complex, unlisted adverse event from a post-marketing ICSR.

4. Signal Detection and Pharmacovigilance Analytics

- Qualitative and quantitative signal detection methods
- Process for signal validation, prioritization, and assessment.
- Application of statistical methods and data mining tools.
- Integration of Real-World Data (RWD) sources into signal surveillance.
- Case Study: Detecting a weak, emerging safety signal using RWD from patient registries and assessing its regulatory implications.

5. Risk Management Systems and RMPs

- Detailed breakdown of the Risk Management Plan (RMP) structure

- Developing robust risk minimization measures (aRMMs).
- Regulatory submission and lifecycle management of the RMP.
- Understanding the PRAC's role in RMP review and acceptance.
- Case Study: Developing a complex RMP for a novel biological product, focusing on specific aRMMs and communication plans.

6. Measuring Effectiveness of Risk Minimization Measures (aRMMs)

- Methodologies for evaluating aRMM effectiveness
- Designing Post-Authorisation Safety Studies (PASS) to assess risk.
- Use of surveys, drug utilization studies, and patient feedback.
- Documentation and reporting of aRMM evaluation results to regulators.
- Case Study: Designing an observational PASS study protocol to measure the impact of a communication campaign on prescribing behavior.

7. Aggregate Safety Reporting

- Mastering the content and structure of PBRER.
- Strategic preparation of Development Safety Update Reports (DSURs) for ongoing trials.
- The transition from PSUR to PBRER and synchronized international reporting.
- Integrating Benefit-Risk Evaluation into aggregate reports.
- Case Study: Analyzing data from multiple sources to write the integrated safety summary section of a PBRER, including a new unlisted risk.

8. Audits, Inspections, and Corrective and Preventive Actions (CAPA)

- Developing an effective PV Audit program
- Strategies for preparing for and managing GVP Inspections
- Effective CAPA plan development, tracking, and closure validation.
- Handling of critical and major findings from regulatory inspections.
- Case Study: Simulating an actual EMA inspection scenario and developing a robust CAPA plan for a critical finding on missing source documents.

9. Pharmacovigilance Quality Management System (QMS)

- Principles of a GVP-compliant QMS (SOPs, training, change control).
- Key Performance Indicators (KPIs) and Quality Indicators (QIs) in PV.
- Ensuring data integrity and reliable audit trails within PV systems.
- Periodic QMS performance monitoring and management review.
- Case Study: Defining a set of PV KPIs for a multi-affiliate organization and establishing a monitoring dashboard.

10. Benefit-Risk Assessment and Decision Making

- Advanced methodologies for qualitative and quantitative B-R assessment.
- Structuring the B-R document for regulatory submission.
- Managing changes to the B-R profile throughout the product lifecycle.
- Communicating the B-R balance to regulators and the public.
- Case Study: Conducting a formal B-R assessment on a drug with known efficacy but a new, serious side effect, leading to a label change recommendation.

11. PV in Clinical Trials and Post-Marketing Interface

- Safety reporting under the EU Clinical Trials Regulation (CTR).
- Managing Suspected Unexpected Serious Adverse Reactions in a global environment.
- Safety data exchange in complex co-development/licensing agreements.
- Transitioning PV activities from clinical to post-marketing phases.
- Case Study: Developing a robust Safety Data Exchange Agreement for a product licensed from a partner company, detailing roles and responsibilities.

12. Crisis Management and Risk Communication

- Defining a PV crisis and developing a structured response plan.
- Effective and transparent risk communication with regulatory authorities and the public.
- Drafting Dear Healthcare Professional (DHCP) letters and press releases.
- Managing social media and media inquiries during a safety issue.
- Case Study: Developing a comprehensive communication plan and drafting a DHCP letter in response to an urgent signal of misuse leading to serious outcomes.

13. Advanced Topics: RWE, AI, and Automation in PV

- Leveraging RWE/RWD from sources like Electronic Health Records for safety.
- The practical application and limitations of AI in PV
- Designing and validating automated PV workflows and computerized systems.
- Regulatory perspectives and guidelines on using AI-driven tools.
- Case Study: Evaluating the ethical and regulatory considerations of implementing an AI-based system for automated literature review and ICSR case intake.

14. Due Diligence and Post-Acquisition PV Integration

- Conducting a PV due diligence audit for in-licensing or acquisition targets.
- Identifying and mitigating PV risks in a merger or acquisition.
- Strategic planning for the PV system integration post-deal closure.
- Review of a partner's PSMF and QMS during due diligence.
- Case Study: Performing a mock PV due diligence on a small biotech, identifying critical gaps in their signal management and PSMF.

15. The Role and Liability of the QPPV

- Detailed review of the QPPV's responsibilities and legal accountability.
- Ensuring QPPV oversight of the entire PV system, including vendors.
- Management of a QPPV team and delegation of tasks.
- Ethical and professional challenges faced by the QPPV.
- Case Study: Analyzing a scenario where a QPPV faces personal liability due to a critical systemic failure and developing a risk management plan for the QPPV function.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.

- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Physical	$12,000

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