Advanced Pharmacovigilance Auditing 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

Pharmacovigilance (PV) is the critical cornerstone of drug safety, globally safeguarding public health by monitoring the safety profile of medicinal products across their entire lifecycle. As global regulatory frameworks become increasingly stringent and complex, the need for expert PV auditors is paramount. Advanced Pharmacovigilance Auditing Training Course is specifically designed for seasoned professionals looking to master the risk-based approach to audits, inspections, and the implementation of robust Quality Management Systems (QMS). It moves beyond foundational knowledge, focusing on strategic planning, third-party oversight, and the auditing of advanced PV technologies such as AI/ML and Real-World Evidence (RWE).

The current drug safety landscape is rapidly evolving, driven by digital transformation and the rise of complex biological products. Effective auditing now requires proficiency in evaluating computerized system validation (CSV), ensuring data integrity, and navigating the complexities of remote audits and global affiliate systems. This course will equip participants with actionable, real-world skills in CAPA management, inspection readiness, and crisis management during regulatory scrutiny. By integrating the latest regulatory intelligence with advanced auditing methodologies, this program ensures graduates become compliance leaders capable of driving pharmacovigilance excellence and upholding the highest standards of patient safety.

Programme Curriculum

Advanced Pharmacovigilance Auditing Training Course

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10 days

Course Objectives

Upon completion, participants will be able to:

1. Develop and implement a Risk-Based Pharmacovigilance Audit Strategy aligned with EMA GVP Module IV requirements.
2. Master the auditing of the entire PV Quality Management System (PV-QMS), including Good Documentation Practice (GDP).
3. Conduct a comprehensive audit of the Pharmacovigilance System Master File (PSMF) integrity and compliance.
4. Evaluate the validation lifecycle of PV databases and computerized systems (CSV) to ensure data integrity (ALCOA+).
5. Design effective audit programs for third-party vendors (CROs), Licensing Partners, and affiliate offices.
6. Audit the core processes of Signal Detection & Management leveraging advanced analytics and AI/ML systems.
7. Assess the compliance of Risk Management Plans (RMPs) and the effectiveness of Risk Minimization Measures (RMMs).
8. Formulate robust Corrective and Preventive Actions (CAPA) and audit their effectiveness checks
9. Lead PV Inspection Readiness activities and successfully manage a regulatory inspection
10. Analyze the use of Real-World Evidence (RWE) and Patient-Centric PV programs within an audit scope.
11. Apply advanced auditing techniques for complex products such as Advanced Therapy Medicinal Products (ATMPs).
12. Handle and mediate challenging audit situations, including disagreement resolution and crisis communication.
13. Stay abreast of global regulatory intelligence and emerging trends like blockchain in data traceability.

Target Audience

1. Pharmacovigilance Quality Assurance (QA) Auditors
2. PV Compliance Specialists
3. Drug Safety & PV Managers

4. Regulatory Affairs Professionals (with PV oversight)
5. Quality Systems Managers
6. QPPV Office/Delegate Staff
7. Clinical Research Associates (CRAs) / Auditing Personnel
8. Senior PV Operations Staff involved in internal audits or hosting inspections

Course Modules

Module 1: The Global PV Regulatory and Quality Landscape

- EU Good Pharmacovigilance Practices (GVP) Modules I, II, III, IV, and XV.
- FDA Pharmacovigilance Inspectional Guidelines and 21 CFR Part 314/600.
- ICH Guidelines on safety and quality.
- PV Audit as the cornerstone of the PV Quality Management System
- Case Study: Analyzing a critical GVP non-compliance finding from a recent EMA inspection report.

Module 2: Strategic Risk-Based PV Audit Planning

- Defining the PV Audit Universe
- Developing the Risk Assessment Methodology for the 3-5-year Audit Strategy.
- Establishing Risk Criteria and prioritizing audit targets based on risk to public health.
- Strategic and Tactical planning.
- Case Study: Designing a risk-based audit plan for a company launching a new product in five different global regions.

Module 3: Auditing the Pharmacovigilance System Master File (PSMF)

- Detailed audit of PSMF Section 1.8 and Annex G
- Verifying the accuracy and contemporaneous nature of the PSMF as the PV system description.
- Auditing the documentation of the Qualified Person for Pharmacovigilance (QPPV) roles and responsibilities.
- Assessing the PSMF's "Always Ready" state for instant regulatory retrieval.
- Case Study: Identifying major discrepancies between the PSMF description and actual PV activities during a mock inspection scenario.

Module 4: Auditing Core Case Processing and ICSR Reporting

- Auditing the compliance of Individual Case Safety Report (ICSR) collection, validation, and expedited reporting timelines.
- Assessing the quality and completeness of Adverse Event (AE) data and source documentation.
- Reviewing the process for External and Internal Safety Data Exchange Agreements (SDEAs) and reconciliation.
- Auditing the completeness of Follow-up Procedures and due diligence documentation.
- Case Study: Identifying the root cause of the delay, from site reporting to final submission.

Module 5: Auditing Signal Detection and Management Systems

- Auditing the process for safety signal identification, validation, and prioritization.
- Evaluating the use of data mining and quantitative methodologies in a signal review.
- Assessing the quality of signal meeting documentation and the decision-making rationale.
- Auditing the interface between PV, Medical Affairs, and Regulatory in signal-related actions.

- Case Study: Auditing a flawed signal detection process that failed to identify an emerging risk across a product line.

Module 6: Auditing Risk Management and Minimization

- Auditing the quality and update process of Risk Management Plans and PV Plans
- Assessing the implementation and compliance of Risk Minimization Measures
- Evaluating the effectiveness of Educational Materials and Direct Healthcare Professional Communications
- Auditing the process for Benefit-Risk Assessment and its impact on product labeling.
- Case Study: Evaluating an audit of a post-authorization safety study (PASS) and the subsequent RMP update.

Module 7: Third-Party Vendor and Affiliate Auditing

- Developing a vendor oversight program and auditing the entire vendor lifecycle
- Auditing Contract Research Organizations for safety data handling in clinical trials.
- Conducting Remote Auditing Techniques and assessing the readiness of local/affiliate PV sites.
- Reviewing the compliance and flow of safety information within Licensing/Distribution Partner SDEAs.
- Case Study: Auditing a major global CRO's safety database migration and data transfer protocols.

Module 8: Advanced Auditing of Computerized Systems

- Auditing Computerized System Validation documentation for PV databases.
- Assessing compliance with 21 CFR Part 11 / Annex 11 on electronic records and electronic signatures.
- Auditing Data Integrity across the entire data lifecycle.
- Reviewing System Change Control and Business Continuity Planning.
- Case Study: Auditing a system access and audit trail review to uncover potential data manipulation.

Module 9: Auditing Artificial Intelligence (AI) and RWE in PV

- Auditing the governance and validation of AI/Machine Learning (ML) tools used for case processing or signal detection.
- Assessing the quality and bias of Real-World Data (RWD) sources used as RWE.
- Auditing the process for incorporating RWE findings into regulatory reports and safety decisions.
- Evaluating the audit trail and transparency of Intelligent Automation in pharmacovigilance workflows.
- Case Study: Auditing the implementation of an AI tool for literature screening and assessing its validation documentation.

Module 10: Corrective and Preventive Action (CAPA) Management Audits

- The principles of a robust CAPA system from investigation to closure.
- Auditing the Root Cause Analysis (RCA) methodology for non-conformities.
- Assessing the quality of the CAPA plan and the linkage of actions to the root cause.
- Auditing the crucial stage of Effectiveness Check (EC) and ongoing monitoring.
- Case Study: Auditing a long-standing CAPA to determine why the underlying systemic issue persists despite multiple corrective actions.

Module 11: PV Inspection Readiness and Management

- Developing a strategic Inspection Readiness Plan and conducting Mock Inspections.
- Preparing the Inspection Team and defining roles and logistics.

- Mastering the techniques for host and auditee interview responses during an inspection.
- Managing the document request process and ensuring timely, compliant delivery.
- Case Study: Simulating a regulatory inspection on short notice, focusing on frontroom/backroom dynamics and stress management.

Module 12: Post-Inspection Activities and Follow-Up

- Handling the Exit Meeting and initial communication of inspection findings.
- Formulating the official Response to the Authority and negotiating timelines for CAPA implementation.
- Auditing the post-inspection CAPA plan for comprehensiveness and commitment.
- Strategies for preparing for and managing a Follow-up/Re-inspection or "for cause" inspection.
- Case Study: Responding to a critical finding and developing a rapid, high-impact CAPA plan.

Module 13: Auditing Specialized PV Topics

- Auditing safety for Advanced Therapy Medicinal Products and other complex biologics.
- Reviewing PV for Medical Devices and Combination Products.
- Auditing the process for Product Quality Complaints (PQCs) and their interface with PV.
- Auditing the process for Unblinding and reporting during clinical trials.
- Case Study: Auditing the long-term safety follow-up system required for a gene therapy product.

Module 14: Advanced Auditor Soft Skills and Communication

- Advanced probing, listening, and evidence-gathering skills.
- Effective Audit Report Writing.
- Techniques for Conflict Resolution and managing resistance during an audit.
- Developing strong pre- and post-audit communication strategies with stakeholders.
- Case Study: Role-playing a challenging interview with a resistant subject matter expert to obtain crucial evidence.

Module 15: Future Trends and Global PV Compliance Challenges

- Impact of ICH E2E and continuous updates in the global regulatory network.
- The role of Blockchain and other emerging technologies in PV data security and traceability.
- Auditing for Patient-Centric Pharmacovigilance and patient support program (PSP) compliance.
- The evolving landscape of EU MDR and its PV implications.
- Case Study: Discussing a current hot-topic regulatory trend and its potential impact on a company's next audit cycle.

Training Methodology

The course employs an **intensive, highly interactive, and practical methodology** designed to simulate real-world auditing challenges.

- Interactive Workshops.
- Detailed Case Studies.
- Role-Playing/Mock Audits.
- Tool & Template Provision
- Expert-Led Sessions.

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
23 Nov 2026	04 Dec 2026	Physical	$12,000

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