Pharmacovigilance and Post-Market Safety Surveillance 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 and Post-Market Safety Surveillance Training Course is designed to provide participants with a comprehensive understanding of drug safety and adverse event reporting. With a growing focus on drug safety monitoring and regulatory compliance, professionals need to stay up-to-date on the latest pharmacovigilance practices. This course covers essential principles, including signal detection, risk management, and adverse drug reaction (ADR) assessment, ensuring that participants gain a solid foundation for their role in protecting public health. Additionally, the course emphasizes the importance of maintaining safety in post-market surveillance through continuous monitoring, reporting, and regulatory frameworks established by agencies like the FDA and EMA.

As the pharmaceutical industry faces increasing scrutiny and global regulatory pressure, organizations must prioritize drug safety. This training equips professionals with the tools to enhance their organization? ÇÖs pharmacovigilance system and drug safety practices. From regulatory requirements to data management strategies, this course provides a well-rounded approach to identifying risks and ensuring compliance. With a focus on cutting-edge pharmacovigilance technologies and data analytics, the course also explores how artificial intelligence (AI) and big data are transforming the landscape of post-market safety surveillance, offering professionals the ability to leverage innovative solutions for improved decision-making.

Programme Curriculum

Pharmacovigilance and Post-Market Safety Surveillance Training Course

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Course Duration

10 days

Course Objectives

1. Understand the principles of Pharmacovigilance and Drug Safety.
2. Gain in-depth knowledge of Adverse Drug Reactions (ADR) reporting and management.
3. Explore regulatory requirements and guidelines for Post-Market Safety Surveillance.
4. Learn to analyze signal detection and assess risk-benefit profiles of drugs.
5. Understand Regulatory Compliance standards like GxP, FDA, and EMA.
6. Implement efficient Pharmacovigilance systems and practices within an organization.
7. Develop the skills necessary for effective data management in Pharmacovigilance.
8. Master the processes of Risk Management and Risk Minimization in drug safety.
9. Examine current pharmacovigilance trends and industry challenges.
10. Learn to identify and manage emerging safety signals using advanced analytics.
11. Understand the impact of global safety regulations on pharmacovigilance strategies.
12. Explore the role of Artificial Intelligence (AI) and Machine Learning in post-market safety surveillance.
13. Learn effective techniques for ADR reporting, documentation, and traceability.

Target Audience

1. Pharmacovigilance professionals.
2. Regulatory Affairs Managers.
3. Clinical Research Associates (CRAs) working in drug safety.
4. Healthcare professionals like doctors and nurses involved in reporting ADRs.
5. Data Scientists specializing in healthcare and drug safety analytics.
6. Quality Assurance professionals.
7. Pharmacy students and graduates.
8. Medical Affairs professionals.

Course Modules

Module 1: Introduction to Pharmacovigilance

- Definition and Scope of Pharmacovigilance
- Importance of Post-Market Safety Surveillance
- Case Study: Regulatory Bodies and Guidelines
- Adverse Drug Reaction (ADR) Classification
- Reporting Requirements and Legal Obligations

Module 2: Regulatory Frameworks

- Global Pharmacovigilance Regulations
- EMA and FDA Guidelines
- ICH E2E Guidelines
- Case Study: GxP Compliance and Best Practices
- Reporting Standards for ADRs

Module 3: Signal Detection & Risk Assessment

- Overview of Signal Detection Techniques
- Statistical Methods in Signal Detection
- Risk-Benefit Analysis of Medicinal Products
- Signal Confirmation and Validation
- Case Study: Tools for Signal Detection and Evaluation

Module 4: Adverse Event Reporting Systems

- EudraVigilance and FDA Adverse Event Reporting System (FAERS)
- MEDWATCH and Other Reporting Systems
- Safety Data Collection and Monitoring
- Case Study: Handling an ADR Report
- Improving the Reporting Process for Drug Safety

Module 5: Risk Management and Minimization

- Principles of Risk Management
- Risk Minimization Plans (RMPs)
- Pharmacovigilance Risk Assessment Tools
- Communication with Healthcare Professionals
- Post-Marketing Surveillance Case Study

Module 6: Pharmacovigilance Data Management

- Data Collection and Analysis
- Pharmacovigilance Databases (e.g., VigiBase)
- Data Integrity and Quality Control
- Analyzing Safety Data Trends
- Case Study: The Role of Databases in Drug Safety

Module 7: Emerging Trends in Pharmacovigilance

- Pharmacovigilance in the Era of Big Data
- Artificial Intelligence and Machine Learning
- Predictive Analytics in Drug Safety
- Case Study: AI in Signal Detection

- Future of Pharmacovigilance

Module 8: Global Pharmacovigilance Practices

- International Pharmacovigilance Standards
- Differences in Global Regulatory Requirements
- Global ADR Reporting and Management
- Cross-border Collaboration in Drug Safety
- Case Study: Global Response to an ADR Crisis

Module 9: Clinical Trials and Pharmacovigilance

- Clinical Trials and Safety Monitoring
- Pharmacovigilance in Phase IV Trials
- Integrating Pharmacovigilance in Clinical Trials
- Clinical Trial Case Study
- Post-Approval Surveillance Strategies

Module 10: The Role of Healthcare Professionals in Pharmacovigilance

- The Role of Physicians and Nurses
- Reporting ADRs in Clinical Settings
- Training Healthcare Professionals
- Case Study: Healthcare Professional Reporting System
- Challenges in ADR Reporting in Healthcare

Module 11: Ethical and Legal Considerations in Pharmacovigilance

- Ethical Issues in Drug Safety Monitoring
- Legal Liabilities in Pharmacovigilance
- Informed Consent and ADR Reporting
- Regulatory Audits and Inspections
- Case Study: Legal Implications of an ADR Incident

Module 12: Documentation and Compliance

- Proper Documentation of ADRs
- Pharmacovigilance Inspection Readiness
- Regulatory Inspection and Audit Compliance
- Case Study: Documentation of Serious ADRs
- Complying with Legal and Ethical Standards

Module 13: Communication in Pharmacovigilance

- Communicating Risk to the Public
- Risk Communication Strategies
- Communicating Safety Information to Stakeholders
- Case Study: Public Health Response to an ADR
- Effective Communication in Crisis Situations

Module 14: Tools and Technologies in Pharmacovigilance

- Software Tools for ADR Reporting

- Risk Management Software
- Pharmacovigilance Databases and Systems
- Integration with Healthcare IT Systems
- Case Study: Implementing New Tools

Module 15: Future of Pharmacovigilance

- Predicting Future Trends in Drug Safety
- Role of Blockchain and AI in Pharmacovigilance
- Personalized Medicine and Drug Safety
- Regulatory Evolution in Pharmacovigilance
- Future Pharmacovigilance Case Study

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
23 Nov 2026	04 Dec 2026	Physical	$12,000

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