Post-Marketing Studies (PMS) and Risk Management 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

Post-Marketing Studies (PMS) and Risk Management are critical components in ensuring that pharmaceutical products, medical devices, and other healthcare products remain safe and effective once they enter the market. In an increasingly regulated environment, having a robust PMS and risk management framework is not only a regulatory requirement but also an ethical obligation to safeguard public health. Post-Marketing Studies (PMS) and Risk Management Training Course provides professionals with in-depth knowledge of PMS and risk management strategies, equipping them with the skills necessary to monitor, assess, and manage the safety of products post-launch. With a focus on real-world case studies and practical applications, this course ensures that learners can navigate complex regulatory landscapes, mitigate risks, and apply cutting-edge techniques to improve patient safety and compliance.

As the healthcare industry evolves, so do the methodologies used in Post-Marketing Studies and Risk Management. Emerging trends such as pharmacovigilance, risk-benefit analysis, and risk minimization strategies are gaining importance, making it imperative for professionals to stay up-to-date with best practices and global standards. This course blends theory and practice, providing participants with a holistic understanding of the field. By incorporating the latest trends, tools, and regulatory frameworks, this training program ensures that learners are equipped to handle the challenges posed by product monitoring and risk management in today?ÇÖs dynamic healthcare environment

Programme Curriculum

Post-Marketing Studies (PMS) and Risk Management Training Course

Introduction

The pharmaceutical and medical device industries are under increasing pressure to demonstrate the long-term safety and effectiveness of their products. This course provides comprehensive training on **Post-Marketing Surveillance (PMS)** and **Risk Management**, equipping professionals with the essential skills to navigate this complex regulatory landscape. We will delve into the critical processes and methodologies required to monitor products after they have been released to the market, ensuring patient safety and maintaining regulatory compliance. Post-Marketing Studies (PMS) and Risk Management Training Course is designed to empower participants with the knowledge to establish robust **pharmacovigilance** and **meddevigilance** systems, manage product lifecycles effectively, and proactively identify and mitigate potential risks.

In a rapidly evolving global market, proactive **risk management** is no longer just a regulatory requirement but a strategic imperative. This training will explore cutting-edge techniques for data analysis, including the use of **real-world evidence (RWE)** and **big data** to detect safety signals. We will cover the development and implementation of **Risk Evaluation and Mitigation Strategies (REMS)** and **Risk Management Plans (RMPs)**, along with the application of **ISO 14971** for medical devices. By the end of this course, participants will be able to design, execute, and report on **post-approval studies**, fulfilling their regulatory obligations while enhancing their organization's reputation for safety and quality.

Course Duration

10 days

Course Objectives

1. Master the principles and regulatory frameworks of **pharmacovigilance** and **meddevigilance**.
2. Design and implement effective **Post-Marketing Surveillance (PMS)** programs.
3. Utilize **real-world evidence (RWE)** and **patient-reported outcomes (PROs)** in safety monitoring.
4. Conduct comprehensive **risk-benefit assessments** throughout a product's lifecycle.
5. Develop and execute **Risk Management Plans (RMPs)** and **Risk Evaluation and Mitigation Strategies (REMS)**.
6. Understand and apply **ISO 14971** for medical device risk management.
7. Analyze and interpret **safety signal detection** data from various sources.
8. Navigate global regulatory requirements, including those from the **FDA, EMA, and ICH**.
9. Develop strategies for effective **product recall** and field safety corrective actions.
10. Implement **data analytics** and **AI tools** for advanced pharmacovigilance.
11. Prepare for and successfully manage **regulatory inspections** related to PMS.
12. Establish and maintain a robust **Quality Management System (QMS)** for safety reporting.
13. Lead and manage cross-functional teams in **lifecycle safety management**.

Target Audience

- Pharmacovigilance Specialists
- Risk Management Professionals
- Regulatory Affairs Managers
- Clinical Safety Scientists
- Clinical Research Associates
- Quality Assurance Managers
- Data Scientists in healthcare
- Medical Affairs and Clinical Operations Personnel

Course Modules

Module 1: Introduction to Post-Marketing Surveillance (PMS)

- Regulatory context and importance of PMS.
- Defining pharmacovigilance and meddevigilance.
- The product lifecycle and the role of post-market activities.
- Global regulatory frameworks (FDA, EMA, ICH).
- Sources of post-marketing safety data.
- **Case Study:** The Vioxx withdrawal and its impact on modern pharmacovigilance regulations.

Module 2: Risk Management Plans (RMPs) & Strategies (REMS)

- Purpose and components of an RMP.
- Development of risk minimization measures.
- Understanding Risk Evaluation and Mitigation Strategies (REMS).
- Differences between RMPs and REMS.
- Regulatory expectations for RMP/REMS submission.
- **Case Study:** The REMS for isotretinoin (Accutane) and the iPLEDGE program.

Module 3: Signal Detection & Safety Analytics

- Principles of signal detection and validation.
- Data mining and advanced analytics techniques.
- Disproportionality analysis (e.g., PRR, ROR).
- Role of big data and AI in identifying safety signals.
- Regulatory requirements for signal reporting.
- **Case Study:** Identifying a new safety signal for a common anti-inflammatory drug through FAERS database analysis.

Module 4: Post-Approval Studies (PAS)

- Types and purpose of post-approval studies.
- Regulatory requirements for PAS commitments.
- Designing and executing non-interventional studies.
- Using real-world evidence (RWE) to fulfill study commitments.
- Communicating results to regulatory authorities.
- **Case Study:** A long-term epidemiological study on the cardiovascular safety of a diabetes medication.

Module 5: Medical Device Risk Management (ISO 14971)

- Introduction to ISO 14971 and its principles.
- The risk management process for medical devices.
- Risk analysis, evaluation, and control.
- Risk-benefit analysis and residual risk assessment.
- Documentation requirements for a risk management file.
- **Case Study:** A case study on a medical device recall due to a software vulnerability identified through a risk management review.

Module 6: Audits & Inspections

- Preparing for a regulatory inspection.
- Types of audits (internal vs. external).
- Common findings and best practices for responding.

- Corrective and Preventive Actions (CAPA) implementation.
- Maintaining a state of inspection readiness.
- **Case Study:** Simulating an FDA inspection and managing a finding related to missing safety data in a PMS report.

Module 7: Global Regulatory Compliance

- ICH guidelines for pharmacovigilance (e.g., E2A, E2B, E2C).
- EU regulations (GVP modules) and the new Medical Device Regulation (MDR).
- FDA's requirements for post-marketing safety reporting.
- Navigating different regional requirements.
- Harmonization of global safety data reporting.
- **Case Study:** Analyzing the differences in reporting timelines for a serious adverse event in the US vs. the EU.

Module 8: Quality Management Systems (QMS) for PMS

- Establishing a robust QMS for pharmacovigilance.
- Standard Operating Procedures (SOPs) for safety reporting.
- Quality control and quality assurance in PMS.
- Documentation and record-keeping best practices.
- Handling deviations and quality events.
- **Case Study:** A quality audit reveals inconsistencies in a company's adverse event data entry, leading to a CAPA plan.

Module 9: Crisis Management & Product Recalls

- Developing a crisis management plan for product safety issues.
- The process of a product recall or field safety corrective action.
- Communication with regulatory authorities and the public.
- Post-recall analysis and lessons learned.
- Preventing future safety incidents.
- **Case Study:** The Tylenol scare of 1982 and the importance of tamper-evident packaging.

Module 10: Role of Real-World Evidence (RWE)

- Introduction to RWE and its sources (EHRs, claims data).
- Regulatory acceptance of RWE in safety surveillance.
- Designing observational studies to generate RWE.
- Challenges and biases in using RWE.
- Integrating RWE into risk management strategies.
- **Case Study:** Using electronic health records to confirm a safety signal for a new antibiotic.

Module 11: Benefit-Risk Assessment

- Frameworks for conducting a benefit-risk assessment.
- Quantitative and qualitative methods.
- Communicating benefit-risk decisions.
- The role of stakeholder engagement (patients, HCPs).
- Benefit-risk throughout the product lifecycle.

- **Case Study:** The balancing act of approving a new cancer drug with significant side effects but life-saving potential.

Module 12: PMS for Combination Products

- Defining and classifying combination products.
- Unique challenges in managing safety for combination products.
- Regulatory reporting requirements (e.g., FDA Form 3500A vs. MedWatch).
- Risk management strategies for complex products.
- Post-market surveillance of drug-device products.
- **Case Study:** A case study on an autoinjector pen where the device component fails, leading to an adverse event.

Module 13: PV & Meddev Vigilance Systems

- Components of a global safety database.
- Implementing and validating a PV or Meddevigilance system.
- Data integrity and security.
- Integration with other corporate systems.
- Selecting the right technology for your organization.
- **Case Study:** An organization's migration to a new safety database and the challenges encountered during data transfer.

Module 14: Safety Communication & Reporting

- Communicating safety information to internal and external stakeholders.
- Regulatory reporting timelines and requirements.
- Preparing periodic safety reports (e.g., PSURs, PADERs).
- Public health advisory and Dear Healthcare Provider letters.
- Best practices for clear and concise safety communication.
- **Case Study:** The communication strategy following a drug-related recall and the role of different channels.

Module 15: The Future of PMS & Risk Management

- Emerging trends in pharmacovigilance.
- Role of machine learning and predictive analytics.
- Challenges and opportunities with digital health technologies.
- The future of regulatory science and global harmonization.
- Ethical considerations in big data and AI for safety monitoring.
- **Case Study:** Using AI to predict potential safety issues for a drug in development based on early clinical data.

Training Methodology

The training will employ a dynamic, blended learning approach to maximize knowledge retention and practical application. The methodology includes:

- Interactive Lectures: Led by industry experts with extensive experience.
- Case Studies & Workshops.
- Group Discussions: Fostering peer-to-peer learning and problem-solving.
- Role-Playing Simulations.

- Quizzes & Assessments: To reinforce key learning points and track progress.

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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