School of Pharmaceutical Sciences & Technology

Curriculum for

Fellowship Program in

PHARMACOVIGILANCE

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Course Title: PHARMACOVIGILANCE
Course Type: FELLOWSHIP
Duration: 360 Hours (can be structured as 24 Credits)
Mode: Lectures, Practicals/Hands-on, Project

Course Description

The Pharmacovigilance course is designed to equip students with essential knowledge and practical skills for monitoring, assessing, and reporting adverse drug reactions (ADRs). With the increasing complexity of therapeutic regimens, ensuring patient safety through effective pharmacovigilance practices has become a cornerstone of healthcare systems. This course provides a foundational understanding of pharmacovigilance concepts, regulatory frameworks, ADR reporting mechanisms, and the role of healthcare professionals in promoting rational and safe drug use. Participants will gain competence in real-world reporting systems, causality assessment, and global safety databases, enabling them to contribute effectively to patient safety and post-marketing surveillance.

Course Objectives: The Course is designed to:

- Understand the principles, objectives, and scope of pharmacovigilance.
- Identify and report adverse drug reactions (ADRs) accurately.
- Familiarize with global pharmacovigilance systems and regulatory requirements.
- Apply causality assessment and signal detection methods in drug safety monitoring.
- Build competency in using standard ADR reporting forms and digital databases.
- Develop professional responsibility and ethical awareness in drug safety reporting.

Course Outcomes: By the end of the course, students will be able to:

CO1: Explain the concept, importance, and historical evolution of pharmacovigilance in healthcare systems.
CO2: Identify and classify various types of adverse drug reactions (ADRs) with examples.
CO3: Understand the structure and functions of national and international pharmacovigilance programs (e.g., PvPI, WHO-UMC).
CO4: Demonstrate skills in ADR reporting using standard forms (CIOMS, CDSCO, WHO VigiBase).
CO5: Apply basic methods of causality, severity, and preventability assessment.
CO6: Describe regulatory obligations of pharmaceutical industries in post-marketing safety reporting.
CO7: Recognize ethical and legal considerations in pharmacovigilance, including patient confidentiality and Good Pharmacovigilance Practices (GVP).

Syllabus

Theory - 10 Credits (150 Lecture Hours)

Module I: Introduction to PV Fundamentals (30 Hrs)

- ✓ Focuses on the core concepts of pharmacovigilance (PV), covering historical milestones like the Thalidomide disaster, objectives, scope, and key definitions such as Adverse Drug Reaction (ADR) and Serious Adverse Event (SAE).

Module II: Adverse Drug Reactions and Assessment (30 Hrs)

- ✓ A detailed study of the classification of ADRs (e.g., Type A, B, C, D) and their underlying biological mechanisms. This module also covers basic assessment methodologies for causality and severity.

Module III: PV Systems and Regulatory Frameworks (30 Hrs)

- ✓ Exploration of the structure and functions of national and international pharmacovigilance programs and regulatory bodies, including the WHO-Uppsala Monitoring Centre (UMC), PvPI, EMA, and FDA. Key ICH guidelines (E2A-F) are also introduced.

Module IV: Data Management and Reporting (30 Hrs)

- ✓ Covers the principles of data collection, quality control, and the use of standard reporting forms (CIOMS I, MedWatch, CDSCO forms). Introduces the use of medical coding dictionaries like MedDRA for standardizing data.

Module V: Signal and Risk Management (20 Hrs)

- ✓ Focuses on post-marketing surveillance principles, signal detection techniques, and the creation of Risk Management Plans (RMPs). Discusses the content and submission requirements for PSURs/PBRERs.

Module VI: Audits, Ethics, and Special Cases (10 Hrs)

- ✓ Study of Good Pharmacovigilance Practices (GVP) and the processes involved in regulatory audits and inspections. Covers essential legal and ethical considerations, including patient confidentiality and PV in vulnerable populations.

Practical/Hands-on Component: 8 Credits (120 Lab Hours)

1. PV Fundamentals Applications: Interactive sessions and case studies designed to help students correctly identify and distinguish between different types of drug-related events in real-world scenarios.
2. Causality Assessment Methods: Hands-on application of formal causality assessment methods, such as the Naranjo scale and WHO-UMC criteria, to determine the likelihood of a drug causing an observed reaction using provided case narratives.
3. Navigating Regulatory Resources: Guided exploration and practical exercises using key online E-Resources such as the FDA MedWatch portal, the EMA GVP guidelines repository, and the PvPI website to access information and forms.

4. Case Processing Simulation: Intensive hands-on practice in a simulated safety database environment (e.g., Argus, ArisGlobal). Activities include end-to-end case intake, accurate data entry, medical coding using MedDRA, and writing regulatory-compliant narratives.
5. Signal Analysis and RMP Drafting: Exercises in analyzing larger pharmacovigilance datasets to identify potential safety signals. Students will also practice drafting key sections of safety reports and conceptualizing a basic Risk Management Plan (RMP).
6. Ethical Scenarios and Audits: Role-playing exercises for audit preparation and case studies focusing on handling ethical dilemmas in data management and patient privacy, ensuring adherence to GVP guidelines.

Project: 6 Credits (90 Self Study/Research Hours)
Projects typically can be selected from the following,

- Analysis of ADRs: Conduct a systematic review and analysis of reported adverse drug reactions for a specific class of drugs.
- Database Management Simulation: Simulate case processing from source documents into a safety database, including coding and report generation.
- Signal Detection Study: Utilize public or simulated data to identify potential safety signals for a given medicinal product.
- Regulatory Compliance Audit: Develop and apply an audit plan to assess a hypothetical company's pharmacovigilance system for compliance with GVP or ICH guidelines.

Textbooks

1. Practical Guide for Pharmacovigilance: The Basics – World Health Organization (WHO)
2. Pharmacovigilance: Principles and Practice – Ronald D. Mann and Elizabeth Andrews
3. Textbook of Pharmacovigilance – Saurabh Bhatia and A.K. Gupta
4. Good Pharmacovigilance Practices (GVP) Modules – European Medicines Agency (EMA)
5. Guidelines for Pharmacovigilance in India – Indian Pharmacopoeia Commission (IPC)

E-Resources

1. WHO Uppsala Monitoring Centre (UMC) – Global pharmacovigilance database and training materials.
2. Pharmacovigilance Programme of India (PvPI) – ADR reporting forms, newsletters, and guidance documents.
3. European Medicines Agency (EMA) – GVP guidelines and signal management tools.
4. U.S. FDA MedWatch – Safety alerts and ADR reporting.
5. WHO Pharmacovigilance Toolkit – Standardized training modules and international best practices.
6. Online Learning Modules on Pharmacovigilance – Offered through WHO Open Learning and Coursera platforms.