FACULTY OF PHARMACY

Marwadi University

B. PHARMACY

Syllabus ◆ Semester-8

Elective subject-**3** name with code: **13PH0805 Pharmacovigilance**

Course Objective

This paper will provide an opportunity for the student to learn about the development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, a global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Course Outcomes

At the completion of this paper, it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance.
3. A national and international scenario of pharmacovigilance.
4. Dictionaries, coding and terminologies used in pharmacovigilance.
5. Detection of new adverse drug reactions and their assessment.
6. International standards for the classification of diseases and drugs.
7. Adverse drug reaction reporting systems and communication in pharmacovigilance.
8. Methods to generate safety data during pre-clinical, clinical and post-approval phases of drugs' life cycle.
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation.
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India.
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning.
12. CIOMS requirements for ADR reporting.
13. Writing case narratives of adverse events and their quality.

Teaching and assessment scheme

Teaching Scheme (Hours)			Credits	Theory/ Tutorial Marks			Practical Marks		Total Marks
Theory	Tutorial	Practical		CSE	IA (I)	ESE (E)	TW	Viva (V)	
3	1	0	4	10	15	75	0	0	100

Theory syllabus **Teaching hours: 45 Hours**

Unit-1 10 Hours

Introduction to pharmacovigilance: History and development of Pharmacovigilance. Importance of safety monitoring of medicine. WHO international drug monitoring programme. Pharmacovigilance program of India (PvPI). Introduction to adverse drug reactions: Definitions and classification of ADRs. Detection and reporting. Methods in causality assessment. Severity and seriousness assessment. Predictability and preventability assessment. Management of adverse drug reactions. Basic terminologies used in pharmacovigilance: terminologies of adverse medication-related events. Regulatory terminologies.

Unit-2 10 Hours

Drug and disease classification: Anatomical, therapeutic and chemical classification of drugs. International classification of diseases. Daily defined doses. International non-proprietary names for drugs. Drug dictionaries and coding in pharmacovigilance: WHO adverse reaction terminologies. MedDRA and standardised MedDRA queries. WHO drug dictionary. Eudravigilance medicinal product dictionary. Information resources in pharmacovigilance: Basic drug information resources. Specialised resources for ADRs. Establishing pharmacovigilance programme: Establishing in a hospital. Establishment & operation of drug safety department in the industry. Contract research organisations (CROs). Establishing a national programme.

Unit-3 10 Hours

Vaccine safety surveillance: Vaccine pharmacovigilance. Vaccine failure. Adverse events following immunization. Pharmacovigilance methods: passive surveillance-Spontaneous reports and case series. Stimulated reporting. Active surveillance-sentinel sites, drug event monitoring and registries. The comparative observational studies-Cross sectional study, case-control study and cohort study. Targeted clinical investigations. Communication in pharmacovigilance: Effective communication in pharmacovigilance. Communication in drug safety crisis management. Communication with regulatory agencies, business partners, healthcare facilities and media.

Unit-4 8 Hours

Safety data generation: Preclinical phase. Clinical phase. Post-approval phase (PMS). ICH guidelines for pharmacovigilance: organization and objectives of ICH. Expedited reporting. individual case safety reports. Periodic safety update planning. Good clinical practice in pharmacovigilance studies.

Unit-5 7 Hours

Pharmacogenomics of adverse drug reactions: Genetics related ADR with example focusing PK parameters. Drug safety evaluation in special population: paediatrics. Pregnancy and lactation. Geriatrics. CIOMS: CIOMS working groups. CIOMS form. CDSCO (India) and pharmacovigilance: D&C Act and Schedule Y. Differences in Indian and global pharmacovigilance requirements.

Tutorials will be based on the above syllabus. **Teaching hours: 15 Hours**

Recommended references (Latest edition)

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Colbert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin NyfortHansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html