18BP090 PHARMACOVIGILANCE

Hours Per Week :

L	T	P	CP	CL
3	1	-	-	4

Total Hours :

L	T	P
45	1	-

WA/RA	SSH/HSH	CS	SA	S	BS

SCOPE:

This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, 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:

Upon completion of the course, the student will be able to achieve the following outcomes:

COs	Course Outcomes	POs	PSOs
1	Why drug safety is monitoring is important	6	1,2
2	History and development of pharmacovigilance	6	1,2
3	National and international scenario of pharmacovigilance	6	1,2
4	Dictionaries, coding and terminologies used in pharmacovigilance	6	1,2
5	Detection of new adverse drug reactions and their assessment	6	1,2
6	International standards for classification of diseases and drugs	6	1,2
7	Adverse drug reaction reporting systems and communication on pharmacovigilance	6	1,2
8	Methods to generate safety data during pre-clinical , clinical and post approval phases of drugs life cycle	6	1,2
9	Drug safety evaluation in pediatrics, geriatrics, pregnancy and lactation	6	1,2
10	Pharmacovigilance program of india (pvpi) requirement for adr reporting in india	6	1,2
11	ICH guide lines for icsr ,psur, expedited reporting , pharmacovigilance planning	6	1,2
12	CIOMS requirements for ADR reporting	6	1,2
13	Writing case narratives of adverse events and their quality	6	1,2

UNIT - I **10HOURS**

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 - II **10 HOURS**

DRUG AND DISEASE CLASSIFICATION

- Anatomical, therapeutic and chemical classification ofdrugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

DRUG DICTIONARIES AND CODING IN PHARMACOVIGILANCE

- WHO adverse reaction terminologies
- Med DRA and Standardized Med DRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

INFORMATION RESOURCES IN PHARMACOVIGILANCE

- Basic drug information resources
- Specialized resources for ADRs

ESTABLISHING PHARMACOVIGILANCE PROGRAMME

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organizations (CROs)
- Establishing a national programme

UNIT - III **10HOURS**

VACCINE SAFETY SURVEILLANCE

- Vaccine Pharmacovigilance
- Vaccination 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
- 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
- Communicating with Regulatory Agencies, Business Partners, Health care facilities & Media

UNIT - IV **8HOURS**

SAFETY DATA GENERATION

- Pre clinical 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 reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

UNIT - V **7HOURS**

PHARMACOGENOMICS OF ADVERSE DRUG REACTIONS

- Genetics related ADR with example focusing PK parameters.

DRUG SAFETY EVALUATION IN SPECIAL POPULATION

- Pediatrics
- Pregnancy and lactation

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (INDIA) AND PHARMACOVIGILANCE

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

RECOMMENDED BOOKS (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 Byron, 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 Wale, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Colbert, Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, and Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills'. 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&mn3=7297
12. http://www.ich.org/
13. http://www.cioms.ch/
14. http://cdsco.nic.in/
15. http://www.who.int/vaccine_safety/en/
16. http://www.ipc.gov.in/PvPI/pv_home.html