PANIPAT INSTITUTE OF ENGINEERING AND TECHNOLOGY

Department of Pharmacy

Course: Bachelore of Pharmacy

LESSON PLAN

Faculty Name: Dr Parveen Goyal **Dr Poonam Ruhal**	**Subject Name: PHARMACOVIGILANCE**
Class: B.Pharmacy 8th Sem	**Subject Code: BP 805T**

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.

Objectives:

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. 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 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)
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

Number of Lectures: 45 **Each Lecture: 01 Hour**

Lecture No.	Particular	Date/ Remark
UNIT-I (10Hrs)		
Introduction to Pharmacovigilance		
1.	History and development of Pharmacovigilance, Importance of safety monitoring of Medicine	
2.	WHO international drug monitoring programme	
3.	Pharmacovigilance Program of India(PvPI)	

Introduction to adverse drug reactions		
4.	Definitions and classification of ADRs , Detection and reporting	
5.	Methods in Causality assessment	
6.	Severity and seriousness assessment	
7.	Predictability and preventability assessment	
8.	Management of adverse drug reactions	
Basic terminologies used in pharmacovigilance		
9.	Terminologies of adverse medication related events	
10.	Regulatory terminologies	
UNIT-II (10 Hrs)		
Drug and disease classification		
11.	Anatomical, therapeutic and chemical classification of drugs	
12.	International classification of diseases , Daily defined doses	
13.	International Non proprietary Names for drugs	
Drug dictionaries and coding in pharmacovigilance		
14.	WHO adverse reaction terminologies ,MedDRA and Standardised MedDRA queries	
15.	WHO drug dictionary, Eudravigilance medicinal product dictionary	
Information resources in pharmacovigilance		
16.	Basic drug information resources ,Specialised resources for ADRs	
Establishing pharmacovigilance programme		
17.	Establishing in a hospital	
18.	Establishment & operation of drug safety department in industry	
19.	Contract Research Organisations (CROs)	
20.	Establishing a national programme	
UNIT-III (10 Hrs)		
Vaccine safety surveillance		
21.	Vaccine Pharmacovigilance ,Vaccination failure	
22.	Adverse events following immunization	
Pharmacovigilance methods		
23.	Passive surveillance – Spontaneous reports and case series	
24.	Stimulated reporting	
25.	Active surveillance – Sentinel sites, drug event monitoring and registries	
26.	Comparative observational studies – Cross sectional study, case control study and cohort study	
27.	Targeted clinical investigations	
Communication in pharmacovigilance		
28.	Effective communication in Pharmacovigilance	
29.	Communication in Drug Safety Crisis management	

30.	Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	
UNIT-IV(8 Hrs)		
Statistical methods for evaluating medication Safety data generation		
31.	Pre clinical phase , Clinical phase , Post approval phase	
ICH Guidelines for Pharmacovigilance		
32.	Organization and objectives of ICH ,	
33.	Individual case safety reports	
34.	Periodic safety update reports	
35.	Post approval expedited reporting	
36.	Pharmacovigilance planning	
37.	Good clinical practice in pharmacovigilance studies	
38.	Expedited reporting	
UNIT-V (7Hrs)		
	Pharmacogenomics of adverse drug reactions **Drug safety evaluation in special population**	
39.	Paediatrics	
40.	Pregnancy and lactation	
41.	Geriatrics	
CIOMS		
42.	. CIOMS Working Groups	
43.	CIOMS Form	
CDSCO (India) and Pharmacovigilance		
44.	D&C Act and Schedule Y	
45.	Differences in Indian and global pharmacovigilance requirements	