INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**BACHELOR OF PHARMACY**
SEMESTER	**8**
COURSE TITLE	**PHARMACOVIGILANCE**
COURSE CODE	**13PH0805**
COURSE CREDITS	**4**

Objective:

1 This course is designed to impart fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like the US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Course Outcomes: After completion of this course, student will be able to:

1 Know about the process of drug discovery and development.

2 Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.

3 Know the regulatory approval process and their registration in Indian and international markets.

Pre-requisite of course: 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.

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
3	1	0	75	15	10	0	0

DR. RAMESH BHANAJIBHAI PARMAR
Digitally signed by (Name of HOD)

DR. LALJI HAKUBHAI BALDANIYA
Digitally signed by (Name of Dean/ Principal)

Contents : Unit	Topics	Contact Hours
1	**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.	10
2	**Drug and disease classification** 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.	10
3	**Vaccine safety surveillance** 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.	10
4	**Safety data generation** 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.	8
5	**Pharmacogenomics of adverse drug reactions** 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.	7
Total Hours		**45**

DR. RAMESH BHANAJIBHAI PARMAR
Digitally signed by (Name of HOD)

DR. LALJI HAKUBHAI BALDANIYA
Digitally signed by (Name of Dean/ Principal)

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
1	**Tutorials** Tutorial 1, Tutorial 2, Tutorial 3, Tutorial 4, Tutorial 5, Tutorial 6, Tutorial 7, Tutorial 8, Tutorial 9, Tutorial 10, Tutorial 11, Tutorial 12, Tutorial 13, Tutorial 14, Tutorial 15	15
Total Hours		**15**

Textbook :

1 Textbook of Pharmacovigilance:, S K Gupta, Jaypee Brothers, Medical Publishers., 2011

References:

1 Practical Drug Safety from A to Z By Barton Colbert, Pierre Biron, Jones and Bartlett Publishers.

2 Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.

3 Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.

4 An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.

5 Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.

6 Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.

7 A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin NyfortHansen, Milap C. Nahata

8 National Formulary of India

9 Text Book of Medicine by Yashpal Munjal

10 Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

11 http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=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

Suggested Theory Distribution:

The suggested theory distribution as per Bloom’s taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery

Remember / Knowledge	Understand	Apply	Analyze	Evaluate	Higher order Thinking / Creative
20.00	30.00	25.00	15.00	10.00	0.00

Instructional Method:

1. The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc.
2. The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.
3. Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.

DR. RAMESH BHANAJIBHAI PARMAR
Digitally signed by (Name of HOD)

DR. LALJI HAKUBHAI BALDANIYA
Digitally signed by (Name of Dean/ Principal)