BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE-PILANI, HYDERABAD CAMPUS
ACADEMIC-GRADUATE STUDIES AND RESEARCH DIVISION
FIRST SEMESTER 2023-2024
Course Handout

Date: 01/08/2023

In addition to Part I (General Handout for all courses appended to the time table) this portion gives further specific details regarding the course.

Course No.	**:**	**PHA G626**
Course Title	**:**	**Pharmacovigilance**
Instructor In-charge	**:**	**Dr. Abhijeet Rajendra Joshi**

1)Course Description: Scope and purpose of pharmacovigilance, safety and Adverse Drug Reactions (ADRs)- causation, pre-clinical, human volunteer, post marketing surveillance studies, signal detection, assessment and risk/crisis management and planning, legislation, regulatory system, WHO, ICH, OECD, Council for International Organizations of Medical Sciences (CIOMS) guidelines, stakeholders perspectives, ethical principles transparency, pharmacovigilance of select organ systems such as cardiovascular, renal and conditions like pregnancy, pediatrics, geriatrics, current limitations and future perspectives, individualized therapy considerations.

2) Scope & Objective of the Course:

This course is intended to provide students with knowledge regarding pharmacovigilance as a science, a basic understanding of the subject, the history of pharmacovigilance in the World, Indian and global scenarios of pharmacovigilance, the process of establishment of pharmacovigilance programs at the organization, various adverse drug reactions and their detection, disease and drug-specific adverse drug reactions and their mechanisms, and WHO and ICH guidelines with respect to pharmacovigilance.

Learning Outcomes (course benefits): Students who have undergone the course are expected to

- understand the terminologies and the working scenario of pharmacovigilance
- know the importance of pharmacovigilance programs and the process of establishment of such programs at the organization
- understand adverse drug reactions, methods of their signal detection, assessment, and reporting system
- understand the safety data generation during clinical trials and post-approval phases of drug
- know the ICH and CIOMS guidelines for pharmacovigilance

3) Text book:

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers, 2nd edition

2. Textbook of Pharmacovigilance, Concept and Practice: Guru Prasad Mohanta, Pharma Med Press, 2nd edition.

Reference Books:

1. Mann's Pharmacovigilance, by Ronald D. Mann Elizabeth B. Andrews, John Wiley and Sons Ltd., 2nd edition
2. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers, 1st edition

3) Course Plan:

Lect. No.	Learning Objectives	Topics to be covered	Chap/Sec No. (Book)
1-6	Introduction to Pharmacovigilance	History of Pharmacovigilance, importance, and purpose of pharmacovigilance, methods of pharmacovigilance	T1-Ch 2, T1-Ch 3, T2-Ch 1
7-9	Vaccine safety surveillance	Types of vaccines, vaccine pharmacovigilance, AEFIs, reporting of AEFIs	T1 -Ch 4, class notes
10-17	Introduction to adverse drug reactions	Definitions and classifications of ADRs, management of ADRs, severity and causality assessments, mechanism of ADRs, adverse drug interactions	T1- Ch 5, class notes
18-22	Organ and condition-specific ADRs	Patterns, detection, and mechanisms of dermatological, gastrointestinal, hematological, hepatic ADR etc. ADRs in pediatric and elderly patients	R1 – Ch 32-36, 40, 42 class notes
23-25	Signal detection and reporting	Sources and methods of signal detection, UMC signaling process, Postmarketing surveillance in India and globally	T1- Ch 6-7, class notes
26-30	Establishing pharmacovigilance programme	Establishing a national programme, establishing pharmacovigilance in hospitals and industries, practicalities involved, Pharmacovigilance program of India (PvPI), pharmacovigilance of ayurvedic, homeopathic drugs, materiovigilance, hemovigilance	T1- Ch 8, T2 – Ch 12-14, class notes
31-32	Benefit-risk assessment in pharmacovigilance	Introduction to benefits-risk assessment, factors affecting, approaches to benefit-risk assessment	T1- Ch 9, class notes

33-34	Introduction to crisis management in pharmacovigilance	Crisis definition, crisis management, case studies related to crisis management in the industry	T1- Ch10, class notes
35-36	Drug and disease classification	Anatomical, therapeutic, and chemical classification of drugs, international non-proprietary names for drugs, international classification of diseases	Class notes, online literature
37-38	Introduction to the medical dictionary for regulatory activities (MedDRA)	MedDRA introduction, structure, and rules of MedDRA	T1- Ch13, class notes
39-40	Regulatory guidelines in pharmacovigilance	ICH guidelines for pharmacovigilance, CIOMS working groups and their tasks,	R1- Ch5, 23; R2- Ch5, 6; class notes

4) Evaluation Scheme:

No.	Evaluation Component	Duration	Weight-age (%)	Date & Time	Nature of Component
1	Surprise quizzes	30 min each	10	Before mid-term	CB
2	Mid-Sem Examination	90 min	25	09/10 4.00 - 5.30PM	CB
3	Surprise quizzes	30 min each	10	After mid-sem	CB
3	Seminar and report	variable	20	Continuous	OB
4	Comprehensive Exam	180 min	35	7/12 AN	CB (15)/OB (20)

5) Mid-Semester Grading: Mid-semester grading will be announced just after Mid sem exam on the basis of marks secured in mid sem and surprise quiz Marks

6) Make-up: Prior approval or intimation to take a make-up is mandatory. It is solely at the discretion of the instructor-in-charge, depending upon the genuineness of the circumstances, to allow or disallow a student to appear for a make-up evaluation component. No makeup will be granted for Assignments/Quizzes under any circumstances.

7) Grading Procedure:

- Grading will be done by "bunching" procedure. Total marks obtained by the students will be arranged in descending order, 'bunches' will be identified and grades awarded accordingly. Fine grading system (A, A-, B, B-….) will be followed.
- It is not mandatory for the instructor-in-charge to award all the grades (A to E); subjective judgment will be used for awarding the grades.
- As specified in Handout – Part I, appended to the timetable, the instructor in-charge reserves the right to award a NC report in case the student does not make himself/ herself available for any of the evaluation component mentioned above.
- Borderline cases during grading will be judged on the basis of regularity to classes and consistency or progress in the performance in evaluation components.

8) Chamber Consultation Hours: To be announced in class.

9) Notices: All the notices pertaining to this course will be displayed only on CMS

10) Academic Honesty and Integrity Policy: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

Instructor-in-charge
PHA G626