NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm)
(Semester - VIII)

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Course Code	**BP805ET**
Course Title	**Pharmacovigilance-Theory**

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.

Objective: At the end of the course, the student shall be able to

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) 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.

Course Learning Outcomes (CLO):

After successful completion of the course, student will be able to -

6. Explain basics of adverse drug reactions and pharmacovigilance.
7. Illustrate drug and disease classification, drug dictionaries, coding, information resources and establishment of pharmacovigilance programme.
8. Outline pharmacovigilance methods, vaccine safety surveillance and communicate with stakeholders in pharmacovigilance.
9. Summarize ICH guidelines for pharmacovigilance and safety data generation
10. Discuss about drug safety evaluation in special population, Pharmacogenomics of adverse drug reactions, CIOMS and CDSCO.

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **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 II **10 Hours**

Drug and disease classification

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

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardized 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 industry
- Contract Research Organisations (CROs)
- Establishing a national programme

UNIT III **10 Hours**

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, Healthcare facilities &
- Media

UNIT IV **08 Hours**

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 **07 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 New Drugs and clinical trials rules 2019
- Differences in Indian and global pharmacovigilance requirements

Tutorials **Teaching Hours: 15 Hours**

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

1. Gupta, S. K. "*Textbook of Pharmacovigilance*." Jaypee Brothers medical publishers (P) Ltd., New Delhi, India
2. Cobert, B., and Pierre B. *Practical drug safety from A to Z*. Jones & Bartlett Publishers, USA.
3. Andrews, Elizabeth B., Nicholas M., eds. Mann's pharmacovigilance. John Wiley & Sons, USA.

4. Talbot, J., Patrick W. Stephens' Detection of New Adverse Drug Reactions. Wiley Publishers, USA.
5. Waller, P., Mira Harrison-Woolrych. *An introduction to pharmacovigilance*. Chichester: Wiley-Blackwell, USA.
6. Cobert, B. *Cobert's manual of drug safety and pharmacovigilance*. Jones & Bartlett Publishers, USA.
7. Strom, B.L., Kimmel S., Hennessy S., eds. *Textbook of pharmacoepidemiology*. John Wiley & Sons, USA.
8. Parthasarathi, G., Karin Nyfort-Hansen, and Milap C. Nahata, eds. A Text Book of Clinical Pharmacy Practice: Essential Concepts and Skills. Orient Blackswan, Hyderabad, India.
9. National Formulary of India, India
10. Munjal, Y.. *API Textbook of Medicine (Volume I & II)*. JP Medical Ltd, India.
11. Mohanta, G.P., Manna, P.K. *Text book of Pharmacovigilance: concept and practice*. PharmaMed Press/BSP Books, India.

L= Lecture, T= Tutorial, P= Practical, C= Credit
^ this is not an exhaustive list