BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

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:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

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.

Course Content

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 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 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

Effective communication in Pharmacovigilance

Communication in Drug Safety Crisis management

Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV **8 Hours**

Statistical methods for evaluating medication safety data

Safety data generation

Pre clinical phase

Clinical phase

Post approval phase

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 **7 hours**

Pharmacogenomics of adverse drug reactions

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

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