

# PHARMACOVIGILANCE (Theory)

## 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

#### **Communication in pharmacovigilance**

- 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 Pharmacoepidemiology 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 Nyfort Hansen, 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/](http://www.who.int/vaccine_safety/en/)
17. [http://www.ipc.gov.in/PvPI/pv\\_home.html](http://www.ipc.gov.in/PvPI/pv_home.html)