BP805ET. PHARMACOVIGILANCE (Theory)

45 hours

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 Standardized MedDRA queries, WHO drug dictionary, EudraVigilance medicinal product dictionary.

Information resources in pharmacovigilance

Basic drug information resources, Specialized resources for ADRs.

Establishing pharmacovigilance programme

Establishing in a hospital, Establishment & operation of drug safety department in industry, Contract Research Organizations (CROs), Establishing a national program.

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**

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 **7 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 Schedule Y**,** Differences in Indian and global pharmacovigilance requirements.

Recommended Books (Latest edition):

- Textbook of Pharmacovigilance by S K Gupta, Jaypee Brothers, Medical Publishers.
- Quintessence of Pharmacovigilance by Tapan Kumar Chatterjee, PharmaMed Press.
- Practical Drug Safety from A to Z by Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
- Mann's Pharmacovigilance by Elizabeth B. Andrews, Nicholas, Wiley Publishers.
- Stephens' Detection of New Adverse Drug Reactions by John Talbot, Patrick Walle, Wiley Publishers.
- An Introduction to Pharmacovigilance by Patrick Waller, Wiley Publishers.
- Cobert's Manual of Drug Safety and Pharmacovigilance by Barton Cobert, Jones & Bartlett Publishers.
- Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
- A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills by G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata, Orient Longman Pvt Ltd.
- National Formulary of India.
- Textbook of Medicine by Yashpal Munjal.
- Textbook of Pharmacovigilance: Concept and Practice by G.P. Mohanta and P.K. Manna.
- http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=7297
- http://www.ich.org/
- http://www.cioms.ch/
- http://cdsco.nic.in/
- http://www.who.int/vaccine_safety/en/
- http://www.ipc.gov.in/PvPI/pv_home.html