B. PHARMACY

Syllabus • Semester-8

Elective subject-3 name with code: 13PH0805 Pharmacovigilance

Course Objective
This paper will provide an opportunity for the student to learn about the development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, a 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.

Course Outcomes
At the 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. A national and international scenario of pharmacovigilance.
4. Dictionaries, coding and terminologies used in pharmacovigilance.
6. International standards for the 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' lifecycle.
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.

Teaching and assessment scheme

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<th>Teaching Scheme (Hours)</th>
<th>Credits</th>
<th>Theory/ Tutorial Marks</th>
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Theory syllabus

Unit-1

Unit-2

Unit-3

Unit-4
8 Hours

Unit-5

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.

Tutorials will be based on the above syllabus.  

Teaching hours: 15 Hours

Recommended references (Latest edition)
2. Practical Drug Safety from A to Z By Barton Colbert, Pierre Biron, Jones and Bartlett Publishers.
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
15. http://cdsco.nic.in/
17. http://www.ipc.gov.in/PvPI/pv_home.html