DEPTH OF BIOLOGY

B. PHARMACY

8 SEM PRACTICE QUESTIONS

PHARMACOVIGILANCE

DEPTH OF BIOLOGY

Unit I

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

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2/3 MARKS

1. Define Pharmacovigilance.

2. What is the full form of PvPI?

3. What are Adverse Drug Reactions (ADRs)?

4. Name any two causality assessment methods.

5. What is the role of WHO in international drug monitoring?

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5/7 MARKS

1.Write a short note on the history and development of pharmacovigilance.

2.Explain the importance of safety monitoring in medicines.

3.Describe the process of detection and reporting of adverse drug reactions.

4.Discuss the assessment of severity and seriousness in ADRs.

5.Write about basic terminologies used in pharmacovigilance.

DEPTH OF BIOLOGY

10/15 MARKS

1. Explain the Pharmacovigilance Program of India (PvPI) and its significance.
2. Define adverse drug reactions (ADRs). Classify ADRs and describe the methods for causality assessment.
3. Discuss the process and importance of predictability, preventability, and management of adverse drug reactions.
4. Elaborate on the WHO International Drug Monitoring Programme and its global impact.
5. Write a detailed note on regulatory and adverse medication-related event terminologies used in pharmacovigilance.

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Unit II

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

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2/3 MARKS

1. What is the significance of International Non-Proprietary Names (INN) for drugs?

2. Define MedDRA in pharmacovigilance.

3. What are Daily Defined Doses (DDD)?

4. Name any two drug information resources used in pharmacovigilance.

5. What does Eudravigilance focus on?

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5/7 MARKS

1. Explain the role of the WHO drug dictionary in pharmacovigilance.
2. Describe the importance of establishing a pharmacovigilance program in hospitals.
3. What are the basic and specialized resources for adverse drug reactions (ADRs)?
4. Write a short note on the Anatomical, Therapeutic, and Chemical (ATC) classification of drugs.
5. Discuss the role of Contract Research Organisations (CROs) in pharmacovigilance.

DEPTH OF BIOLOGY

10/15 MARKS

1. Explain the process and significance of drug and disease classification in pharmacovigilance.
2. Describe the structure and use of MedDRA and Standardized MedDRA Queries in pharmacovigilance.
3. Outline the steps involved in establishing a pharmacovigilance programmed at the national level.
4. Discuss the importance and usage of different drug dictionaries and coding systems in pharmacovigilance.
5. Explain the role and operation of a drug safety department in the pharmaceutical industry.

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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

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2/3 MARKS

1. What is vaccine pharmacovigilance?

2. Define vaccination failure.

3. What is meant by passive surveillance in pharmacovigilance?

4. Give two examples of active surveillance methods.

5. Mention two key points for effective communication in pharmacovigilance.

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5/7 MARKS

1. Explain the significance of adverse events following immunization (AEFI) in vaccine safety surveillance.
2. Differentiate between passive and stimulated reporting in pharmacovigilance.
3. Write a short note on targeted clinical investigations in pharmacovigilance.
4. Describe the role of communication in drug safety crisis management.
5. Explain the importance of communicating with regulatory agencies and business partners during a pharmacovigilance process.

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10/15 MARKS

1. Discuss the various pharmacovigilance methods, including passive, stimulated, and active surveillance.
2. Elaborate on the concept of vaccine safety surveillance, highlighting vaccine pharmacovigilance, vaccination failure, and adverse events following immunization.
3. Explain the comparative observational studies in detail, including cross-sectional study, case-control study, and cohort study.
4. Describe the significance of effective communication in pharmacovigilance and the challenges faced during drug safety crisis management.
5. Write an essay on the role of communication in pharmacovigilance, especially focusing on regulatory agencies, healthcare facilities, business partners, and media.

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Unit IV

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

DEPTH OF BIOLOGY

2/3 MARKS

1. What is the pre-clinical phase in safety data generation ?
2. Define Post Marketing Surveillance (PMS).
3. What is expedited reporting in pharmacovigilance ?
4. State the full form of ICH and its main objective.
5. What are Individual Case Safety Reports (ICSRs)?

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5/7 MARKS

1. Describe the stages involved in safety data generation.

2. Write a short note on the objectives and structure of ICH.

3. Explain the purpose and importance of Periodic Safety Update Reports (PSURs).

4. Discuss the significance of pharmacovigilance planning.

5. Explain the role of Good Clinical Practice (GCP) in pharmacovigilance studies.

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10/15 MARKS

1. Explain in detail the process of safety data generation across pre-clinical, clinical, and post-approval phases.
2. Discuss the ICH Guidelines for Pharmacovigilance — including expedited reporting, ICSRs, PSURs, and post-approval expedited reporting.
3. Elaborate on the role and importance of Pharmacovigilance Planning in the drug development process.
4. Describe the principles of Good Clinical Practice (GCP) and its application in pharmacovigilance studies.
5. Write a detailed note on the structure, objectives, and global role of ICH in standardizing pharmacovigilance practices

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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

DEPTH OF BIOLOGY

2/3 MARKS

1. What is pharmacogenomics of adverse drug reactions?

2. Name two special populations considered in drug safety evaluation.

3. What does CIOMS stand for?

4. Mention any one function of CDSCO in pharmacovigilance.

5. What is Schedule Y under the Drugs and Cosmetics Act?

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5/7 MARKS

1. Explain the role of genetics in adverse drug reactions (ADR) with an example.

2. Discuss the challenges of drug safety evaluation in pregnancy and lactation.

3. Write a short note on the CIOMS Form and its purpose.

4. Describe the importance of drug safety monitoring in geriatrics.

5. Explain the differences between Indian and global pharmacovigilance requirements.

DEPTH OF BIOLOGY

10/15 MARKS

1. Describe pharmacogenomics and its significance in predicting adverse drug reactions, including an example related to pharmacokinetic (PK) parameters.
2. Discuss the considerations for drug safety evaluation in special populations: pediatrics, pregnancy and lactation, and geriatrics.
3. Explain the role of CIOMS Working Groups and the CIOMS Form in global pharmacovigilance practices.
4. Elaborate on the D&C Act and Schedule Y in the context of pharmacovigilance in India.
5. Compare and contrast Indian and global pharmacovigilance requirements, highlighting key regulatory differences.