Code: 15R00707

R15

B.Pharm IV Year I Semester (R15) Regular & Supplementary Examinations February 2022

PHARMACOVIGILANCE

Time: 3 hours Max. Marks: 70

PART – A

(Compulsory Question)

*****

1 Answer the following: (10 X 02 = 20 Marks)

(a) Write the need of pharmacovigilance.
(b) What is cohort monitoring?
(c) What is mean by individual case safety report?
(d) What is pharmacovigilance inspection?
(e) Enumerate the various pharmacovigilance methods.
(f) Define drug event monitoring.
(g) Define adverse drug reaction.
(h) Write in short about reporting systems.
(i) What is communication in pharmacovigilance?
(j) What is business partners pharmacovigilance?

PART – B

(Answer all the questions: 05 X 10 = 50 Marks)

2 Write in detail about the history and development of pharmacovigilance.

OR

3 (a) Write why pharmacovigilance needed in drug safety
(b) Write about the WHO international drug monitoring programme.

4 (a) Discuss the roles and responsibilities in pharmacovigilance.
(b) Write about the information resources in pharmacovigilance.

OR

5 Write the types, designing, maintenance and training SOP for pharmacovigilance.

6 Explain in detail about the active and passive surveillance methods.

OR

7 (a) Write short notes on cohort studies.
(b) Write short notes on stimulated reporting.

8 Explain in detail about the guidelines for reporting of ADRs in biomedical literature.

OR

9 Write in detail about introduction and spontaneous reporting system.

10 (a) Write short notes on communicating with health care facilities and media.
(b) Write short notes on communicating with Doctor Letters to Healthcare Professionals.

OR

11 Write in detail about the communication and effective communication in pharmacovigilance.

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Code: 15R00707

R15

B.Pharm IV Year I Semester (R15) Regular & Supplementary Examinations February/March 2021

PHARMACOVIGILANCE

Time: 3 hours Max. Marks: 70

PART – A

(Compulsory Question)

*****

1 Answer the following: (10 X 02 = 20 Marks)

(a) Write a note on phase-II studies.
(b) Write the objectives of pharmacovigilance program in India.
(c) Write the abbreviations of ICH and DCGI.
(d) Write the primary sources of pharmacovigilance.
(e) Explain adverse drug event.
(f) What is sentinel site?
(g) Define causality.
(h) Specify time required for spontaneous reporting system.
(i) Enlist various communication methods in pharmacovigilance.
(j) Define drug safety.

PART – B

(Answer all five units, 5 X 10 = 50 Marks)

UNIT – I

2 Describe the global prospective method of surveillance of medication.

OR

3 Write a note on WHO international drug monitoring program.

UNIT – II

4 Explain the information resources in pharmacovigilance.

OR

5 (a) Write a note on license partners.
(b) Write a note on market authorization holders.

UNIT – III

6 Discuss the pros and cons of cohort event monitoring.

OR

7 (a) Discuss about active surveillance.
(b) Write a note on passive surveillance.

UNIT – IV

8 Explain the guidelines for the reporting of adverse drug reactions in biomedical literature.

OR

9 Explain the mechanisms of adverse drug reactions.

UNIT – V

10 Discuss about communication in drug safety crisis management.

OR

11 Explain the procedure involved in educating the healthcare professionals with effective communicating regarding adverse drug reaction reporting.

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Code: 15R00707

R15

B.Pharm IV Year I Semester (R15) Supplementary Examinations October 2020

PHARMACOVIGILANCE

Time: 3 hours

Max. Marks: 70

PART – A

(Compulsory Question)

*****

1 Answer the following: (10 X 02 = 20 Marks)

(a) Define pharmacovigilance
(b) What is Uppsala monitoring centre?
(c) What is adverse drug reaction?
(d) Write the type of SOPs.
(e) What is CRO?
(f) What are registries?
(g) Write about audit reporting.
(h) What is a periodic safety update reports?
(i) Define drug safety crisis management.
(j) List out the type of communication in pharmacovigilance.

PART – B

(Answer all five units, 5 X 10 = 50 Marks)

UNIT – I

2 Explain the history and development of pharmacovigilance in health care system.

OR

3 Discuss the current status of pharmacovigilance programme in India.

UNIT – II

4 Describe the establishment of pharmacovigilance department in hospital.

OR

5 Discuss the various roles & responsibilities of CROs in pharmacovigilance.

UNIT – III

6 Explain the passive surveillance methods in detail.

OR

7 Describe about the comparative observational study with example.

UNIT – IV

8 Explain the spontaneous reporting system.

OR

9 List out and explain the reports to be sent to regulatory authorities.

UNIT – V

10 Explain various communication methods involved in pharmacovigilance.

OR

11 Explain the barrier of communication for effective management of ADR monitoring.

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Code: 15R00707

R15

B.Pharm IV Year I Semester (R15) Regular & Supplementary Examinations November/December 2019

PHARMACOVIGILANCE

Time: 3 hours Max. Marks: 70

PART – A

(Compulsory Question)

*****

1 Answer the following: (10 X 02 = 20 Marks)

(a) Define ADR.
(b) What is CDSCO?
(c) What is market authorization holder?
(d) List out the documents in establishing ADR monitor centre in hospital.
(e) What is case series?
(f) What is stimulated reporting?
(g) Write about causality assessment in ADR monitoring.
(h) What is guideline of ADR reporting?
(i) Define communication.
(j) List out the barrier of communication in pharmacovigilance.

PART – B

(Answer all five units, 5 X 10 = 50 Marks)

UNIT – I

2 Explain the importance of safety monitoring.

OR

3 Discuss the WHO international drug monitoring programme.

UNIT – II

4 Discuss the establishment and operation of drug safety department in industry.

OR

5 Explain about the Contract Research Organizations.

UNIT – III

6 Discuss about the active surveillance method.

OR

7 Describe the case control study and cohort study with example.

UNIT – IV

8 Discuss the guidelines for submitting adverse event reports for publication.

OR

9 Explain the spontaneous reporting system in ADR monitoring.

UNIT – V

10 Explain about the communication in drug safety crisis management.

OR

11 Explain the regulatory agencies of ADR monitoring.

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Code: 15R00707

R15

B.Pharm IV Year I Semester (R15) Supplementary Examinations June 2019

PHARMACOVIGILANCE

Time: 3 hours | Max. Marks: 70

PART – A

(Compulsory Question)

*****

1 Answer the following: (10 X 02 = 20 Marks)

(a) Define the term "Adverse drug reaction".
(b) Why monitoring of ADR is required?
(c) What is causality assessment?
(d) How do you categorize adverse drug reactions?
(e) What is a cross-sectional study in ADR monitoring?
(f) Write note on sentinel sites.
(g) What are the various ADR reporting systems?
(h) How to report an ADR in biomedical literature?
(i) List down the various methods of communication in pharmacovigilance.
(j) What is drug safety crisis management?

PART – B

(Answer all five units, 5 X 10 = 50 Marks)

UNIT – I

2 Describe the history & development of pharmacovigilance.

OR

3 Discuss the importance of safety monitoring in pharmacovigilance.

UNIT – II

4 Discuss the roles and responsibilities of CROs in pharmacovigilance.

OR

5 Explain the establishment & operation of drug safety department in an industry.

UNIT – III

6 Discuss various passive & active surveillance methods in ADR monitoring.

OR

7 Compare between cross-sectional, case-control & cohort study in pharmacovigilance methods.

UNIT – IV

8 Discuss the various guidelines for reporting ADRs in biomedical literatures.

OR

9 Explain the methods of ADR reporting.

UNIT – V

10 Describe the importance of communication with healthcare professionals in pharmacovigilance.

OR

11 Discuss the role of communication in drug safety crisis management.

*****

Code: 15R00707

R15

B.Pharm IV Year I Semester (R15) Supplementary Examinations June 2019

PHARMACOVIGILANCE

Time: 3 hours | Max. Marks: 70

PART – A

(Compulsory Question)

*****

1 Answer the following: (10 X 02 = 20 Marks)

(a) Define the term "Adverse drug reaction".
(b) Why monitoring of ADR is required?
(c) What is causality assessment?
(d) How do you categorize adverse drug reactions?
(e) What is a cross-sectional study in ADR monitoring?
(f) Write note on sentinel sites.
(g) What are the various ADR reporting systems?
(h) How to report an ADR in biomedical literature?
(i) List down the various methods of communication in pharmacovigilance.
(j) What is drug safety crisis management?

PART – B

(Answer all five units, 5 X 10 = 50 Marks)

UNIT – I

2 Describe the history & development of pharmacovigilance.

OR

3 Discuss the importance of safety monitoring in pharmacovigilance.

UNIT – II

4 Discuss the roles and responsibilities of CROs in pharmacovigilance.

OR

5 Explain the establishment & operation of drug safety department in an industry.

UNIT – III

6 Discuss various passive & active surveillance methods in ADR monitoring.

OR

7 Compare between cross-sectional, case-control & cohort study in pharmacovigilance methods.

UNIT – IV

8 Discuss the various guidelines for reporting ADRs in biomedical literatures.

OR

9 Explain the methods of ADR reporting.

UNIT – V

10 Describe the importance of communication with healthcare professionals in pharmacovigilance.

OR

11 Discuss the role of communication in drug safety crisis management.

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