Code No: E-12441/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I-Semester (PCI) (Backlog) Examination, November-2023

Subject: Good Regulatory Practices

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Write a note on Global Harmonization Task Force (GHTF) guidance documents. [8]
   (b) Write a note on WHO cGMP guidelines. [7]

2. (a) Explain the types of Audits and Audit tools. [10]
   (b) What are the goals of laboratory Quality Audit? [5]

3. (a) Explain the CFR Part 210. [5]
   (b) Describe USFDA GLP Regulations. [10]

4. (a) Describe the general check list of 21 CFR Part 11. [8]
   (b) Describe principles and SOPs of GALP. [7]

5. (a) Write about Principles and Documentation in Good Distribution Practices. [8]
   (b) Write a note on USP GDP. [7]

6. (a) Describe Six Sigma concept. [5]
   (b) Explain Quality by Design tool for Quality Management. [10]

7. (a) Write a note on Types of Validation. [7]
   (b) Explain about ICH guidelines. [8]

8. (a) Describe ISO and QCI standards for GALP. [8]
   (b) Explain about HVAC validation. [7]

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Code No: E-12442/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Documentation and Regulatory Writing

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Explain the importance of EPDB for drug substance and drug products. [7]

   (b) Explain the batch formula records in detail. [8]

2. (a) Describe the contents of Site Master File. [10]

   (b) What is product development report (PDR)? Discuss the significance of PDR. [5]

3. (a) Describe the modules of ICH-CTD format with granularity. [10]

   (b) Define and compare paper CTD and electronic CTD. [5]

4. (a) Describe the aim , requirement and organization of ASEAN Common Technical Dossier (ACTD). [9]

   (b) Write a note on Electronic Submission gateways. [6]

5. (a) Discuss the internal and external Audits in detail. [8]

   (b) Explain the purpose of Global Harmonization Task Force (GHTF) study group 4 guiding document. [7]

6. (a) Write a detailed note on Pre-approval Inspections. [7.5]

   (b) Outline FDA inspection process for drug distribution channels. [7.5]

7. (a) Discuss the Post Approval Changes (SUPAC) process for an approved drug product. [10]

   (b) Write a note on Prior approval supplement. [5]

8. Write short notes on

   (a) Importance and steps involved in root cause analysis. [7.5]

   (b) CBE 30. [7.5]

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Code No: E-12443/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Clinical Research Regulations

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Write a note on Phase I and Phase III clinical trials. [6]
   (b) Write a note on Clinical Trial protocol. [9]

2. (a) Describe the Historical perspectives that resulted in ethics to be followed in clinical research. [10]
   (b) Describe the Informed consent process. [5]

3. (a) Write a note on clinical research regulations in Europe Union (EMA) [9]
   (b) Describe guidelines for Medical Devices in India. [6]

4. (a) Explain the ICH E6 guidelines with regard to Good Clinical Practice. [9]
   (b) Describe ICMR ethical guidelines for biomedical research. [6]

5. (a) Write a note on CFR 21 Part 50 with regard to protection of human subjects. [9]
   (b) Explain ISO 14155. [6]

6. Discuss about
   (a) ANDA 505(j) of the FD&C Act. [5]
   (b) Responsibilities of sponsor, CRO and investigator in ethical conduct of clinical research. [10]

7. Write a note on
   (a) Europe union Eudralex volume 3 guidelines. [10]
   (b) ICH E9 with regard to general biostatics principle applied in clinical research. [5]

8. Write a note on
   (a) Randomized clinical trials. [8]
   (b) Instituitonal review board. [7]

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Code No: E-12444/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical regulatory Affairs) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Regulations and Legislation for Drugs and Cosmetics, Medical Devices, Biologicals and Herbal and Food and Nutraceuticals in India and Intellectual Property Rights

Time: 3 Hours **Max.Marks:75**

Note: Answer any five questions. All questions carry equal marks.

1. a) What are Medical Devices? Describe the regulations and guidelines for approval of Medical devices.
   b) Describe the content and format for preparation of clinical trial dossier. [9+6]

2. Describe the objective of DPCO and NPPA. Explain the methods of price fixation of bulk drugs, formulations and new drugs. [15]

3. a) Define the terms Advertisement, Magic remedies, Nutraceuticals, Cosmetics and formulations.
   b) Describe the organization, functions and responsibilities of state pharmacy council. [7+8]

4. a) What is patent? Write about the objectives, rights of patentee.
   b) Define Intellectual Property Rights. Narrate the types of IPRs. [6+9]

5. What are the objectives of?
   a) Pharmacy act; b) Narcotic drugs and Psychotropic substances act;
   c) CPCSEA; d) CDSCO e) Medicinal and Toilet preparation act. [15]

6. a) Explain the constitution and functions of Pharmacy council of India. [7+8]
   b) Give an informative note on Copyrights.

7. a) Differentiate between bonded and non bonded laboratory. Describe the construction of bonded laboratory. [8+7]
   b) Give an informative note on CPCSEA guidelines on animal experimentation.

8 a) Describe the regulatory requirement for conducting BA and BE studies [8+7]
   b) Write an informative note on ICH guidelines for stability studies.

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