Exam Date & Time: 25-Nov-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Good Regulatory Practices [PQA-MRA101T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) In a tablet manufacturing unit, following observations were made by USFDA inspectors. State which part and section of cGMP is violated and suggest corrective actions for the same. (10)

- White powder found on the exterior surface of the manufacturing equipment.
- One batch of the product failed in assay.

2) Differentiate between ISO 17025 and GLP. (10)

3) SHAACH laboratories, Aurangabad has decided to implement LIMS system for its laboratory data management. What are responsibilities of director and vice presidents of the company? (10)

4) List the responsibilities of a 'Responsible person" in a Pharmaceutical Distribution Firm as per EU GDP guidelines. (10)

5) Explain Analytical method validation in detail (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) What is the meaning of 21CFR210.2 and when is it revised? (5)

7) What should a company check before installing LIMS software regarding security of the system? (5)

8) Define the following as per 21CFR11. (5)

- Closed System.
- Open system.
- Procedural controls
- Technological Controls
- Biometrics

PTO

9) List the premises requirements of a wholesale distributor as per EU GDP guidelines.

10) Discuss in detail about six sigma concepts in pharma industry (5)

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am Date & Time: 27-Nov-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Documentation and Regulatory Writing [PQA-MRA102T]

Duration: 180 mins.

Marks: 75

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Prepare a sample template for the document which is mandatory while procuring an API from vendor. Explain the part of this document. (10)

2) Write the similarities and differences between Australian and EU NeeS application. (10)

3) US FDA is going to conduct a regulatory audit at Emcure Pharma. Explain the phases involved in this audit. (10)

4) An out of specification result was observed for water content test (6.5 %) in Rabeprazole API batch no: A901234. Water content specification is 4.0- 6.0 %. Explain the steps and tools used in root cause analysis of this investigation. (10)

5) How to classify the process related post approval changes? Write in detail about the test documentation to be provided to the regulatory agency. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) What are the electronic submission gateways ? Write the difference between CTD and ACTD submissions. (5)

7) Explain the types of inspection carried out in a GMP site. (5)

8) Explain the documents to be verified while conducting an audit of Purchasing control subsystem at medical device manaufacturer premise. (5)

9) Differentiate between warning letter and form 483. (5)

10) Suggest any five major changes which required to be filed in prior approval supplement. (5)

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am Date & Time: 29-Nov-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Clinical Research Regulations [PQA-MRA103T - S2]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) What are the regulatory guidance of FDA on Phase II clinical trials. Discuss the "end of Phase II meetings". (10)

2) Explain the seven recommendations of Belmont report. (10)

3) Write the composition and functions of IRB. Write the GCP guidance on "Informed consent". (10)

4) Discuss the scope of ICH E7 guidelines. Critically evaluate its guidance. (10)

5) What are the contents of an NDA application? (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) What is dose escalation study? Discuss the "traditional 3+3 design with the help of a flow chart. (5)

7) What is 505(b)(2) application? (5)

8) Explain the age classification of paediatric population as per ICH E11. (5)

9) Discuss the stages of clinical evaluation and the process involved with the help of a flow chart. (5)

10) Discuss the phase IV trials of post marketing surveillance programme. (5)

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Date & Time: 02-Dec-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Regulations and Legislation for Drugs and Cosmetics - Medical Devices - Biologicals and Herbals and [PQA-MRA104T - S3]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Describe the types of pricing in DPCO 2013. (10)

2) A. Explain the functions of Institutional Animal Ethics Committee (5 Marks)
B. Mention the global classification of herbals on basis of origin, quality and safety. (5 Marks) (10)

3) A. Enlist the contents of Quality profiling of a drug to be submitted for attaining marketing authorization. (5 Marks)
B. Discuss the procedure to be adapted by a pharmaceutical manufacturer in India to attain license for marketing the recently developed drug under CDSCO. (5 Marks) (10)

4) Mention the competent authorities and guidelines involved in registration of biologics under CDSCO and draw a flow chart on biologics approval process in India. (10)

5) Mention the requirements to establish the stability of new drug substances and products as per ICH guideline. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Biocon Pharmaceuticals is planning to launch a product from human stem cells, what are the studies prohibited in India under CDSCO. (5)

7) Enlist the salient features of the latest Clinical Trials rules 2019 and write a note on clinical trial management systems. (5)

8) Enlist the requirements for an animal study as mentioned in CPSCEA guidelines. (5)

9) Define copyrights and explain the subject matters that CANNOT BE protected under copyrights. (5)

10) Enlist the circumstances where the government allows third party to produce the (5)

patented product or process without the consent of the patent owner with exampl

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Drug Reg.

Exam Date & Time: 28-Dec-2019 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Documentation and Regulatory Writing [PQA-MRA102T - S2]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Write the factors to be considered while planning for regulatory submission and publishing? (10)
Give a comparison between paper submission process and e-submission process.

2) Pharma Lab is planning to launch a new biologics in 2030. Explain the strategies involved in creating and executing a product development plan for the new biologics. (10)

3) Which sites tigger a facility evaluation for a pre-approval inspection ? (10)
Explain the risk based priority inspection criteria for pre-approval inspections.

4) Explain the documents to be verified while conducting an audit of design and development subsystem at medical device manaufacturer premise. (10)

5) Discuss the different reporting categories of filing the post approval changes to already approved dossier. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Explain the auditing approaches to conduct an audit at medical device manufacturer. (5)

7) List the applications, which can be sumitted through SUGAM. (5)

8) Prepare a checklist for the inspection of a drug distribution channel. (5)

9) Critically comment on Case A, Case B, and Case C dissolution scenarios with respect to test documentation of post approval changes. (5)

10) Prepare the list of DOs and DONTs while answering the queries of inspector. (5)

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