Question Paper

Exam Date & Time: 27-Nov-2017 (02:00 PM - 05:00 PM)

MANIPAL UNIVERSITY

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM : MPHARM SEMESTER I
DATE : 27-11-2017
TIME : 2:00PM - 5:00PM
Good Regulatory Practices [PQA-MRA101T]

Duration: 180 mins.

Marks: 50

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1) What are the concepts of GAMP-5? Explain MES life cycle approach. (5)

2) Write the GLP inspection checklist which assist in self-regulatory preparation. (5)

3) Write the general checklist of 21 CFR part 11. (5)

4) Write a note on GDP as per CDSCO guidance. (5)

5) Give the reasons for disqualification of testing facilities. What are the actions taken on disqualification? (5)

6) What are the legal requirements and documentation requirement for GDP. (5)

7) Explain process validation in detail. (5)

8) Explain out of specification in detail with the help of a flowchart. (5)

b

nswer the following with specific answers (2 marks x 5 = 10 ma Arks)

9) List any four importance of quality by design (2)

A) (2)

B) Write the principle of GALP. (2)

C) Compare 21 CFR part 11 and EU GMP annex 11 (2)

D) What are the quality system requirements as per IMDRF and 21 CFR part 820 for medical devices? (2)

E) Give diagrammatic representation of V model design for GAMP. (2)

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ate & Time: 29-Nov-2017 (02:00 PM - 05:00 PM)

MANIPAL UNIVERSITY

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM: MPHARM SEMESTER 1
DATE: 29/11/2017
TIME: 2:00PM - 5:00PM

Documentation and Regulatory Writing [PQA-MRA102T]

Duration: 180 mins.

arks: 50

nswer all the questions.

nswer the following (5 marks x 8 = 40 marks)

List the items reported in the inspection report as per WHO GMP. (5)

Explain types of audit, preparation and conducting audit of manufacturing facilities. (5)

Write a note on ISO 13485 (5)

) What are the steps involved in CAPA in a pharmaceutical industry. (5)

) Write a note on SUPAC for immediate release products and modified release for change in batch size and manufacturing site. (5)

;) What is exploratory product development brief? Explain (5)

7) What documents are required to be submitted for the Import and Registration of the bulk drug(s) and finished product(s) in India as per CDSCO? (5)

8) List the various dossiers submitted to USFDA during each stage of drug development and explain their content in brief.

Answer the following with specific answers (2 marks x 5 = 10 marks)

9) Draw the Process Flow for Multiple Site Auditing as per GHTF study group 4 guidelines. (2)

A)

B) What is Establishment Inspection Report? Give any two examples for commonly found cGMP violation? (2)

C) What is the general protocol followed by the FDA during a voluntary recall? (2)

D) List the types of DMF as per USFDA. (2)

E) List the advantages of eCTD.

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xam Date & Time: 01-Dec-2017 (02:00 PM - 05:00 PM)

MANIPAL UNIVERSITY

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM : MPHARM SEMESTER I
DATE : 01-12-2017
TIME : 2:00PM - 5:00PM

Clinical Research Regulations [PQA-MRA103T]

Marks: 50 **Duration: 180 mins.**

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1) Briefly describe the regulations of pediatric investigation of medicinal products as per ICMR and ICH (5)

2) List the modules of GVP (Good Vigilance Practices) and explain Module II and Module V in detail. (5)

3) Define medical devices and classify them according to USFDA. Write a short note on approval procedure of medical devices followed under European Union (5)

4) What are audits? Mention the types of audits and steps involved in certification audit as per ISO (5)

5) Write a brief note on Clinical Trial Site management and Clinical trial management. (5)

6) Write a brief note on phase III clinical trials (5)

7) Describe the contents of ANDA in brief. (5)

8) Discuss the regulatory requirements for the conduct of pharmacokinetic study to establish bioequivalence (5)

b

Answer the following with specific answers (2 marks x 5 = 10 marks)

9) List the regulatory bodies governing medicinal products in US under USFDA (2)

A)

B) Enlist the contents of Schedule Y as per Drugs and cosmetics act 1940. (2)

C) Differentiate between single ascending and multiple ascending trials (2)

D) Write the Title I and Title II of Hatch Waxman Act (2)

E) Enlist the contents of a NDA application (CTD format) (2)

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Question Paper

Exam Date & Time: 04-Dec-2017 (02:00 PM - 05:00 PM)

MANIPAL UNIVERSITY

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM : MPHARM SEMESTER I
DATE : 04-12-2017
TIME : 2:00PM - 5:00PM

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

Marks: 50 **Duration: 180 mins.**

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1)	Define patent and enlist criteria for granting patent and steps in filing a patent application in India.	(5)
2)	Explain the provisions for bonded manufacturing.	(5)
3)	Write the objective of pharmacy act and functions of pharmacy council of India.	(5)
4)	Compare bioequivalence guidelines of India and USA.	(5)
5)	Write a short note on regulatory requirements and approval procedure for attaining marketing authorization of biologics in US.	(5)
6)	Draw a flow chart on central and state regulatory governance of India.	(5)
7)	Give a pictorial representation on contents of regulatory dossier filing and give in detail the index of quality profile during such submissions.	(5)
8)	Write about the categories of research on stem cells as per ICMR-DBT guideline.	(5)

Answer the following with specific answers (2 marks x 5 = 10 marks)

9)	What is copyright? enlist and explain its types.	(2)
A)		
B)	What are medical devices? Classify them with suitable examples as per CDSCO.	(2)
C)	Write the functions of animal welfare board of India.	(2)
D)	Write on the BCS classification of drug with appropriate examples.	(2)
E)	What is the difference between indigenous herbal medicines, herbal medicines, modified herbal medicines and imported herbal medicines in system?	(2)