Exam Date & Time: 29-Mar-2021 (01:30 PM - 04:30 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Clinical Research Regulations [PQA-MRA103T]

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

SECTION - A

Answer all the questions.

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

1) Explain the new drug development process with a regulatory perspective. (5)

A)

B) Write a regulatory overview of Phase 1 clinical trials. (5)

2) Analyse briefly the regulatory requirements of Phase 2 trials. (5)

A)

B) Discuss the types and purpose of "end of phase 2" meetings. (5)

3) Explain the thalidomide incident leading to Declaration of Helsinki (10)

4) What is the purpose of conducting "dose-response" studies? Discuss the study design proposed by ICH E4. (5)

A)

B) Discuss the pharmacokinetic studies mandated by ICH E7. (5)

5) What is "informed consent"? Write the requirements of an informed consent as per 21CFR part 50. (5)

A)

B) Discuss the basic elements of an informed consent. (5)

SECTION - B

Answer all the questions.

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

6) Explain the ethical demands of randomized clinical trials. (5)

7) Why care to be taken while doing the clinical trials in special population? (5)

8) What is GCP? Write the principles of ICH GCP. (5)

9) Analyse and discuss the importance of ICH E8 guidelines on study data. (5)

10) What is 'Clinical hold"? Discuss the clinical hold process. (5)

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