Question Paper

Exam Date & Time: 27-Nov-2023 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Clinical Research Regulations [PRM-MRA103T]

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

SECTION - A

Answer all the questions.

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

1)	Explain Clinical Drug Development Process. Discuss the regulatory process in approving the new drug "BI-5000 in subjects with Type 2 Diabetes Mellitus" in to the US market. (4+6)	(10)
2)	Compose an Informed Consent Form for a clinical study "A Prospective, Randomised, Double-blind, Placebo controlled, Phase-II by III Study to Evaluate Safety, Reactogenicity, Tolerability and Immunogenicity of CORBEVAX Vaccine in Children and Adolescents". Explain the process and documentation of informed consent. (7+3)	(10)
3)	Explain the general principles of ICH GCP E6 guideline.	(10)
4)	Analyze the requirements for the conduction of clinical trials in paediatric populations as per ICH guidance.	(10)
5)	Discuss the "New Drug Application format" as per the USFDA guidance 21 CFR Part 314.	(10)

SECTION - B

Answer all the questions.

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

6)	Explain various stages of clinical evaluation for Medical Devices and IVD's	(5)
7)	Classify the control groups and explain their role in clinical trials	(5)
8)	"A strong Institutional Ethics Committee is required for fair conduct of clinical research in India". Justify the statement.	(5)
9)	Compare and contrast Clinical Trial Regulation (NDCT 2019) and Schedule Y	(5)
10)	Write a note on ISO 14155.	(5)

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