Exam Date & Time: 16-Dec-2022 (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 [PQA-MRA103T - S2]**

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

## SECTION - A

**Answer all the questions.**

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

1) Explain the principles of ICH-GCP E6 guideline. Give a short note on Nuremberg code. (7+3) (10)

2) Explain various phases of clinical trials. Add a note on multicentre trial study. Discuss on scenario of clinical trials during COVID-19. (5+2+3) (10)

3) Explain Medical Device Approval Pathway as per USFDA. Add a note on Humanitarian Device Exemption. (8+2) (10)

4) Explain the clinical investigation of medicinal products in geriatric population as per ICH guidance. Enlist the difference in the governance of clinical trial for pharmaceuticals under USFDA and EMA. (5+5) (10)

5) Explain the key highlights of New Drugs and Clinical Trial Rules 2019. (10)

## SECTION - B

**Answer all the questions.**

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

6) Prepare a template for clinical trial protocol for an antidiabetic drug. (5)

7) Explain the case that led to the origin of Pharmacovigilance worldwide. Add a note on pharmacovigilance program of India. (5)

8) Mention the structure and functions of an Institutional Ethics committee. (5)

9) Write a note on Periodic Safety update Reports under European Medicines Agency. (5)

10) Explain 505 b(2) application process. How is it different from 505 (j) application? (5)

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