

Exam Date & Time: 05-Dec-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
Specialization: Pharmaceutical Regulatory Affairs
Date: 05-12-2018
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) Discuss the principles and sources of data used in a clinical evaluation of a medical device as per GHTF (10)
- 2) Discuss the BA/BE requirements of FDA (10)
- 3) What are the types of control groups in clinical trials? Discuss the ICH guidelines on "placebo control" and "External control" (10)
- 4) What is the purpose of a "dose response" trial? Discuss the ICH guidelines on the same. (10)
- 5) Explain the types of reviews in clinical trials. (10)

SECTION - B

Answer all the questions.

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

- 6) Discuss the methods to minimize bias in clinical trials as per ICH (5)
- 7) What are the types of Paediatric studies? Discuss the age classification. (5)
- 8) Write the objectives and considerations of "Phase III" clinical research (5)
- 9) Write the role of placebo in clinical trials (5)
- 10) Write the structure and importance of Periodic safety update reports. (5)

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