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.

Regulatory Affairs [PMA-MPD103T]

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

SECTION - A

Answer all the questions.

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

1) Explain role of WHO, WTO, WIPO and ICH. Add a note on drug regulations pertaining to US, EU, UK, Japan and India. (10)

2) Write in brief about GCP, GMP and GLP. Add brief note on category of cosmeceuticals and nutraceuticals in different parts of the world market. (10)

3) Write the composition and responsibilities of Institutional Review Board. Add note on informed consent. (10)

4) Define medical devices. Classify medical devices as per Indian regulatory system and add a note on CTD and benefits of eCTD. (10)

5) What is non-clinical study? Explain the types of non-clinical studies. (10)

SECTION - B

Answer all the questions.

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

6) Explain concept of complex generics. (5)

7) Describe steps involved in Drug Discovery and Development process. (5)

8) Define Pharmacovigilance. Explain the two scales used for classification of ADR's. (5)

9) Explain objectives of Hatch-Waxman Act. (5)

10) Discuss some unfortunate events that catalysed the development of medicines regulation. (5)

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