Exam Date & Time: 11-Mar-2022 (10:00 AM - 01:00 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)	Name countries that are classified as regulated and semi-regulated market. Explain role of WHO, WTO, WIPO and ICH.	(10)
2)	Discuss category of cosmeceuticals in different parts of the world market. Drug discovery and development process is complex. Comment. Add note on Artificial Intelligence (AI) in drug discovery and development process. (4+6= 10 marks)	(10)
3)	Write the composition and responsibilities of Institutional Review Board. Add note on informed consent.	(10)
4)	Define and classify Nutraceuticals and Medical Devices. Add note on regulatory status of nutraceuticals in various countries.	(10)
5)	What do you mean by Investigational New Drug Application? Explain the types of IND. What information's should the IND application contain?	(10)

SECTION - B

Answer all the questions.

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

6)	Complex generics are challenging, time-consuming and expensive. Comment.	(5)
7)	What is clinical trial protocol? Discuss various parts of protocol.	(5)

8)	When are the bioequivalence studies carried out? Explain post marketing surveillance system of various countries.	(5)
9)	Explain objectives of Hatch-Waxman Act.	(5)
10)	What is difference between Law, Rules and Regulation? Discuss some unfortunate events that catalysed the development of medicines regulation.	(5)

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