

# 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.

### Regulatory Affairs [PRM-MPH104T - S2]

Marks: 75

Duration: 180 mins.

#### SECTION - A

Answer all the questions.

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

- 1) What is difference between Law, Rules and Regulation? Discuss some unfortunate events that catalysed the development of medicines regulation. Add a note on classification of global market. (10)  
(2+3+5=10 marks)
- 2) Explain in brief drug approval process followed in EU and India. Add note on global professional societies. (10)
- 3) What are complex generics? Add note on various services outsourced for BA/BE studies. (10)  
(4+6=10marks)
- 4) Define medical device. Classification of medical devices as per Indian regulatory system. Add note on regulatory scenario of Biotechnology products in India. (10)
- 5) Explain types of non-clinical studies. Add a note on Investigational Medicinal Product Dossiers. (10)

#### SECTION - B

Answer all the questions.

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

- 6) Explain principal medicines regulatory functions. (5)
- 7) Describe steps involved in Drug Discovery and Development process. (5)
- 8) Explain role and responsibilities of regulatory professionals in pharmaceutical companies. (5)
- 9) Explain objectives of Hatch-Waxman Act. (5)
- 10) Mention the name of regulatory authority of Hong Kong, China, Thailand, South Africa and Brazil. (5)

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