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.

**Regulatory Affairs [PMA-MPH104T - S3]**

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

## SECTION - A

**Answer all the questions.**

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

1) Drugs need to be regulated in developed and developing countries.Comment. Discuss drug approval process in India and functions of CDSCO. Add note on skills required and responsibilities of regulatory professional in pharmaceutical companies. (8+2=10 marks) (10)

2) Explain in brief about role and classification of nutraceuticals and cosmeceuticals in healthcare field. Add note on regulatory status of nutraceuticals and cosmeceuticals in different countries. (10)

3) Explain objectives of Hatch-Waxman Act and add a note on complex generics and biosimilars. (10)

4) Classify medical devices as per Indian regulatory system and add a note on benefits of eCTD and composition of ICH-Steering Committee. (4+3+3=10 marks) (10)

5) Discuss significance and status of post marketing surveillance in major countries. Explain required and additional elements of Informed consent. (10)

## SECTION - B

**Answer all the questions.**

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

6) Mention the name of regulatory authority of Nigeria, Costa Rica, China, Singapore and Uganda. (5)

7) Drug Discovery and Development process is important process in pharmaceutical field. Comment. (5)

8) Enlist types of non clinical studies. Add a note on Investigational Medicinal Product Dossier. (5)

9) Write a short note on master formula record and distribution records. (5)

10) Discuss parts of protocol (clinical trials) in detail. (5)

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