

# Question Paper

Exam Date & Time: 24-Nov-2023 (10:00 AM - 01:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

### Documentation and Regulatory Writing [PRM-MRA102T]

Marks: 75

Duration: 180 mins.

#### SECTION - A

Answer all the questions.

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

- 1) Discuss the structure of NeeS and ACTD formats. (10)
- 2) Enlist and explain different types of audits. Elaborate on the process of audit. (10)
- 3) Who holds the primary responsibility to issue, entry, review and control BMR? Discuss stepwise process of issuing, entry, review and control of BMR. (10)
- 4) Present comparative narration of Prior approval submission, Changes being effected and annual report in Life Cycle Management. (10)
- 5) What are the regulatory guidelines governing CAPA? Discuss the steps involved in CAPA (10)

#### SECTION - B

Answer all the questions.

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

- 6) Elaborate on the steps involved in SUGAM submission of CDSCO (5)
- 7) How batch reconciliation is performed? Discuss. (5)
- 8) Discuss the WHO guidance for inspection establishments in the drug distribution chain when pharmaceutical products are suspected to be counterfeit, spurious or substandard. (5)
- 9) Present the stepwise process form notice of inspection to close-out letters. (5)
- 10) Discuss the Post approval labelling changes. (5)

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