Exam Date & Time: 14-Dec-2022 (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 [PQA-MRA102T - S2]

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

SECTION - A

Answer all the questions.

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

1) Who holds the primary responsibility to issue, entry, review and control BMR? Discuss stepwise process of issuing, entry, review and control of BMR. (10)

2) Comparatively discuss the requirements of paper CTD and eCTD submissions. (10)

3) Enlist and explain general investigational tools for root cause analysis. (10)

4) Present different regulatory considerations at different stages of lifecycle management. (10)

5) Present comparative narration of internal audits, external audits and regulatory audits. (10)

SECTION - B

Answer all the questions.

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

6) Present the template content of warning letters, response letters and closeout letters. (5)

7) Explain Process of corrective and preventive actions. (5)

8) Write a detailed note on ISO 13485. (5)

9) What is the importance of electronic submission gateways? Write the names of ESGs of USFDA and CDSCO. (5)

10) How batch reconciliation is performed? Discuss with suitable example. (5)

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