Exam Date & Time: 09-Mar-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) Explain the objectives of auditing the Corrective and Preventive Action (CAPA) subsystem. (10)

2) Write the contents of distribution records.

a.) (2)

b.) Write the difference between the Master Formula Record and Batch Formula Record. (2)

c.) Explain the strategies considered in a product development plan. (6)

3) Which sites trigger a facility evaluation for a pre-approval inspection?

a.) (2)

b.) Explain the risk based priority inspection. (8)

4) Explain the preparatory activities to be carried out before establishing a successful connection with the FDA electronic submission gateway. (10)

5) Explain SUPAC guideline to Industry for Modified Release Solid Oral Dosage Forms with respect to Manufacturing Equipment Changes and Manufacturing Process Changes. (10)

SECTION - B

Answer all the questions.

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

6) Write the application of corrective and preventive action in the product lifecycle. (5)

7) Write a note on Post approval labelling changes. (5)

8) Explain the criteria for auditing medical device supplier premises as per Global Harmonization Task Force (GHTF). (5)

9) Discuss warning letter with one case study. (5)

10) Explain the term "Validation of submission" in eCTD submissions. (2)

a.)

b.) Explain the severity levels in the validation criteria for eCTD submissions. (3)

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