Exam Date & Time: 27-Mar-2021 (01:30 PM - 04:30 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Documentation and Regulatory Writing [PQA-MRA102T]

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

SECTION - A

Answer all the questions.

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

1) Gen Pharma is planning to market anti-psychotic product in US market in the year 2030. As a market research analyst of the company, answer the following questions:
a. When is exploratory research conducted? (1 M)
b. At which stage of exploratory product development the risk is identified? (1 M)
c. Explain the strategies considered in a product development plan. (8 M) (10)

2) Out of specification (OOS) assay result was reported for the Ramipril tablet 2.5 mg batch no.: GL607898. Tablet compression machine malfunction was observed during manufacturing of this batch. As a manufacturing supervisor, explain the steps and tools involved in the root cause analysis in this case. (10)

3) a. Explain the term "Validation of submission" in eCTD submissions? (2 M)
b. Explain the severity levels in the validation criteria for eCTD submissions. (8 M) (10)

4) a. Explain the differences between internal and external audit. (4 M)
b. Explain the contents of audit report in a regulatory audit. (6 M) (10)

5) The formulation of a tablet dosage form was upgraded from the existing formula in the following respect

SN	Component	± %w/w Change
1	Filler	+3%
2	Starch	-2%
3	Lubricant	-1%

(10)

Under which category this change should be notified to the regulatory agency. What test documentation is expected by the regulatory agency to approve this change?

SECTION - B

Answer all the questions.

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

6) Explain the steps involved in design and development of quality management system of medical devices. (5)

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

8) a. Write the structure for Common Technical Document (CTD).
b. Write the differences between ASEAN CTD and ICH CTD. (5)

9) Differentiate between Case-B and Case-C dissolution testing followed to support the post approval changes. (5)

10) Write a note on Changes Being Effected (CBE) and CBE-30. (5)

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