Exam Date & Time: 12-Dec-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Good Regulatory Practices [PQA-MRA101T]

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

SECTION - A

Answer all the questions.

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

1) Discuss cGMP requirements for finished pharmaceuticals pertaining to a) Organization and personnel b) Buildings and Facilities as per USFDA. Whether the cGMP regulations permit the destruction of an internal quality assurance report once corrective action has been completed? Given reason. (8+2=10marks) (10)

2) Discuss a) Organization and Personal b) Facility according to 21 CFR Part 58. Can the organisation chart of a test facility include functions other than those described in the Good Laboratory Practices Principles, such as head of department, coordinator of the study directors, laboratory technician, personnel responsible for veterinary services, etc.? (8+2=10marks) (10)

3) a) Write short notes on External and Internal Laboratory Audit. What is checked during an internal laboratory audit? When does an external laboratory is conducted and how frequently an internal audit has to be conducted?
b) Discuss general principles of Good Automated Laboratory Practices. (5+5=10marks) (10)

4) Describe the similarities between World Health Organization and CDSCO Good Distribution Practices guidelines. (10)

5) Enlist quality guidelines put forwarded by ICH. Discuss in brief Pharmaceutical Quality System. (3+7=10 marks) (10)

SECTION - B

Answer all the questions.

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

6) Discuss in brief the principles of WHO good manufacturing practices for pharmaceutical products. What is the EU Directive for cGMP? (4+1=5marks) (5)

7) Write short notes on future of Good Laboratory Practices (GLP) regulations. What is OECD? Who have established the GLP guidelines for the first time? (4+1=5marks) (5)

8) Write short notes on the Good Distribution Practices guidelines established globally. Is temperature monitoring at all times mandatory during the distribution of pharmaceuticals in India? (4+1=5marks) (5)

9) Discuss the principles of Total Quality Management. What is Deming Cycle? (4+1=5marks) (5)

10) Enlist various types of validation and discuss anyone. What is IQ, OQ and PQ? (4+1=5marks) (5)

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