Question Paper

Exam Date & Time: 22-Nov-2023 (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 [PRM-MRA101T]

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

SECTION - A

Answer all the questions.

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

1)	Discuss USFDA current good manufacturing practices requirements for a) Control of Components and Drug Product Containers and Closures b) Production and Process Controls. How many containers of each component from each shipment must a firm sample and test to comply with the cGMP regulations for identity testing? 8+2=10 marks	(10)
2)	Discuss Protocol for and Conduct of a Non-clinical Laboratory Study as per 21 CFR 58. What are the roles and responsibilities of a Test Facility and IT provider when GLP data are retained by an IT provider that is not part of a GLP monitoring program? (8+2=10marks)	(10)
3)	a) What does a Laboratory Audit Examine or areas of laboratory audit? Give a brief account on ISO 17025 and ISO 15189? b) Discuss in brief Good Automated Laboratory Practices principles and requirements. (5+5=marks)	(10)
4)	Discuss principles of Good Distribution Practices. Name a few companies that are obliged to comply with GDP. (8+2=10marks)	(10)
5)	Discuss in brief the history of ICH. Discuss in brief ICH topics. Discuss the need for carcinogenicity studies of pharmaceuticals. (2+4+4=10marks)	(10)

SECTION - B

Answer all the questions.

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

6)	What is Good Automated Manufacturing Practices? Add a note on the benefits of GAMP-5. Is GAMP a code of practice or mandatory requirement? (1+3+1=5marks)	(5)
7)	What is Quality Council of India and how it is relevant to Good Laboratory Practices? Enlist the subparts in 21CFRPart58? (3+2=5 marks)	(5)
8)	Mention the aspects that are to be considered while effective implementation of Good Distribution Practices.	(5)
9)	What is the concept of Six Sigma? Discuss DMAIC. Give an example for common cause variation and special cause variation.	(5)
10)	Discuss with an example Minor, Major and Critical Change. Is change control a regulatory requirement and mandatory to document?	(5)

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