Exam Date & Time: 07-Mar-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)	What are the responsibilities of "Head of Production" and "Head of Quality Control" as per EU GMP?	(10)
2)	How does ISO/IEC 17025 differs from US GLP? Explain.	(10)
3)	Prepare a checklist for auditing a bespoke software.	(10)
4)	Write an organogram for a pharmaceutical distribution company as per WHO GDP guidelines. Briefly explain the job responsibilities of each in the organogram.	(10)
5)	Design an analytical method validation protocol as per the requirement of ICH guidelines	(10)

SECTION - B

Answer all the questions.

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

6)	Explain FIVE key concepts of GAMP 5 guidelines.	(5)
7)	Write a flow chart for automation of content uniformity testing for prednisolone tablets as per GALP guidelines. The assay method followed is UV spectroscopy.	(5)
8)		(5)

Amunis Pharmaceuticals manufactures metformin hydrochloride at its Manipal plant, transports the same to a facility at Mangalore where it is converted to granules and sells them to customers at Chennai and Bangalore. To what operations does the WHO GDP guidelines applicable to this and why?

9) Discuss in detail about validation master plan (5)

10) Explain the importance of cleaning validation with the help of any case studies (5)

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