Question Paper

Exam Date & Time: 24-Nov-2023 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Quality Management Systems [PQA-MQA102T - S2]

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

SECTION - A

Answer all the questions.

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

1)	Discuss in detail about dimensions of quality with relevant examples.	(10)
2)	AnPro Laboratories is operating a clinical pathology laboratory. Can they get NABL accredition? If YES, what will the process for the same?	(10)
3)	Explain the risk management approached used in vendor evaluation, qualification and requalification in pharmaceutical industry.	(10)
4)	Explain the risk ranking and filtering with the help of a case study	(10)
5)	The granules of atenolol tablets should be dried between 390C (LSL) and 490C (USL) in a fluid bed drier. The operational temperature of the drier has an average value of 400C and standard deviation of 20C. calculate the process capability of the process.	(10)

SECTION - B

Answer all the questions.

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

6)	What are the principles of Total Quality Management? Explain in brief.	(5)
7)	Explain the significant issues and concerns due to failure in facility and equipment system in pharmaceutical manufacturing unit.	(5)
8)	A product has an acceptable composite assay range of 90.0 to 110.0 percent. The initial (OOS) assay result is 89.5 percent. Subsequent sample preparations from the original sample yield the following retest results: 99.0, 98.9, 99.0, 99.1, 98.8, 99.1, and 99.0 percent. A comprehensive laboratory investigation (Phase 1) fails to reveal any laboratory error. Review of events during production of the batch reveals no aberrations or indication of unusual process variation. Review of the manufacturing process and product history demonstrates that the process is robust. Explain an action plan for the batch and batch disposition.	(5)
9)	Explain the importance of ICH Q1E guidelines	(5)
10)	Explain the key stages of benchmarking and their impact on the company's efficiency and competitiveness in the pharmaceutical research & development.	(5)

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