Question Paper

Exam Date & Time: 17-May-2024 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Audits and Regulatory Compliance [PQA-MQA203T -S2]

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

SECTION - A

Answer all the questions.

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

1)	Discuss information gathering and its importance in regulatory inspections, discuss the administration of the same.	(10)
2)	Discuss in detail about role of quality systems and audits in pharmaceutical manufacturing environment.	(10)
3)	Design an audit checklist for sterile production and packaging	(10)
4)	Discuss in detail the critical points to be discussed in the design of the ETP audit checklist	(10)
5)	Prepare a checklist for auditing a microbiological laboratory.	(10)

SECTION - B

Answer all the questions.

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

6)	Classify the deficiencies in an audit and explain the impact of critical deficiencies on the regulatory inspection	(5)
7)	What is an audit checklist, and give its importance	(5)
8)	Discuss in detail the points to be considered during the preparation of a beta-lactam antibiotic capsule production facility audit checklist	(5)
9)	Explain the administrative and regulatory requirement of Clinical trial site as per US National Institute of Health (NIH).	(5)
10)	Write the considerations for sampling and sample handling in microbiology laboratories as per GLP.	(5)

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