Exam Date & Time: 18-Jul-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

AUDITS AND REGULATORY COMPLIANCE [PQA-MQA203T-S1]

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 information gathering and its importance in regulatory inspections, discuss the administration of the same.	(10)
2)	Discuss in detail about system-based audit approach with suitable examples	(10)
3)	Prepare a detailed audit checklist for an sterile production and packaging as per cGMP requirement	(10)
4)	Write GMP audit checklist for HVAC in a non-sterile pharmaceutical facility	(10)
5)	Prepare checklist for auditing for personnel, environment and cleaning of microbiology lab.	(10)

SECTION - B

Answer all the questions.

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

6)	Explain the impact of major deficiencies during the regulatory inspection, Discuss the same with relevant case study	(5)
7)	Discuss in detail about importance of cGMP regulations on controlling quality systems	(5)
8)	Discuss in detail about points to be considered during preparation of audit checklist for a raw material, in process and finished product facility of generic drug manufacturing facility	(5)
9)	Give a comparative chart for HVAC parameters in sterile and non- sterile area.	(5)
10)	Explain different types of microbiological test method used for environmental monitoring.	(5)

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