

Exam Date &amp; Time: 11-Sep-2021 (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]**

**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) Prepare a detailed audit checklist for a generic drug industry working for US market. (10)
- 3) Prepare a detailed audit checklist for an bulk pharmaceutical chemicals and packaging material vendor as per cGMP requirement (10)
- 4) Prepare a detailed audit checklist for critical utility systems used for pharmaceutical facility (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) How does an auditor gather information during an audit? Explain in detail (5)
- 7) Discuss in detail about quality system approach in an audit (5)
- 8) Discuss in detail about possible critical quality attributes to be considered for preparing an audit checklist for sterile production and packaging (5)
- 9) Explain in detail about auditing of ETP in a pharmaceutical facility (5)
- 10) Write the considerations for sampling and sample handling in microbiology laboratories as per GLP. (5)

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