Exam Date & Time: 01-Dec-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
Specialization: Pharmaceutical Regulatory Affairs
Date: 01-12-2018
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) Explain water system validation in detail. (10)

2) Explain the quality system requirements of pharmaceutical product distributors as per CDSCO draft GDP guidelines. (10)

3) Write a note on "Sub Part F - production and process control" as per US GMP. (10)

4) Prepare a laboratory audit checklist of analytical testing facility with detailed explanation. (10)

5) Define the following as per GALP guidelines.
Acceptance testing, Documentation, LIMS Raw Data, Records, Software version control. (10)

SECTION - B

Answer all the questions.

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

6) Discuss in detail about the concept of six sigma system in pharmaceutical industry. (5)

7) Explain the importance of ISO 13485 in detail. (5)

8) Write a note on "Product Quality Review" as per EU GMP. (5)

9) Write a note on personal in LIMS implementation. (5)

10) What is the scope of WHO GDP guidelines? (5)

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