03-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: 03-12-2018
Documentation and Regulatory Writing [PQA-MRA102T]

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

SECTION - A

Answer all the questions.

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

1) Explain in detail about the audit program for a manufacturer with multiple sites as per GHTF group 4 guidance. (10)

2) Write the differences and similarities between Australia and European NeeS submission. (10)

3) Explain the strategies involved in creating and executing a product development plan. (10)

4) Explain the quality system requirements for national GMP inspectorate. (10)

5) Discuss post approval manufacturing process changes with required documentation in detail. (10)

SECTION - B

Answer all the questions.

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

6) Explain the stages involved in Australian DMF registration system. (5)

7) What is quality audit? Explain different types in brief. (5)

8) Explain the steps involved in CAPA with flow diagram. (5)

9) Differentiate between form 483 and warning letter. (5)

10) Explain the procedure of complaint investigation (5)

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