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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e: 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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Dr. Sudheer - Manipal
PQA MRA 103T

me: 05-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: 05-12-2018
Clinical Research Regulations [PQA-MRA103T]

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

SECTION - A

Answer all the questions.

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

1) Discuss the principles and sources of data used in a clinical evaluation of a medical device as per GHTF (10)

2) Discuss the BA/BE requirements of FDA (10)

3) What are the types of control groups in clinical trials? Discuss the ICH guidelines on "placebo control" and "External control" (10)

4) What is the purpose of a "dose response" trial? Discuss the ICH guidelines on the same. (10)

5) Explain the types of reviews in clinical trials. (10)

SECTION - B

Answer all the questions.

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

6) Discuss the methods to minimize bias in clinical trials as per ICH (5)

7) What are the types of Paediatric studies? Discuss the age classification. (5)

8) Write the objectives and considerations of "Phase III" clinical research (5)

9) Write the role of placebo in clinical trials (5)

10) Write the structure and importance of Periodic safety update reports. (5)

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Exam Date & Time: 07-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: 07-12-2018
Regulations and Legislation for Drugs and Cosmetics - Medical Devices - Biologicals and Herbals and [PQA-MRA104T]

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

SECTION - A

Answer all the questions.

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

1) What is patent? Explain the steps in filing a patent application in India. (10)

2) Explain the central regulatory governance and drug approval process in India. (10)

3) Write a note on Schedule Y under D&C act 1940 and briefly explain on clinical trial management systems (10)

4) Enlist the Table of Contents (TOC) of quality, animal and human data for regulatory filing. (10)

5) Write a note on various designs of stability testing of new drugs and products as per ICH with appropriate examples (10)

SECTION - B

Answer all the questions.

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

6) Differentiate between Drug Price Control Order and National Pharmaceutical Pricing Authority of India. (5)

7) Explain the provisions of bonded manufactory. (5)

8) Enlist the acts and regulations governing animal testing in India. (5)

9) Mention the responsibilities of drug inspector as per D&C act 1940. (5)

10) Mention the organogram of Medical Device regulations under CDSCO. (5)

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