Question Paper

Exam Date & Time: 29-Nov-2017 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM: MPHARM SEMESTER 1
DATE: 29/11/2017
TIME: 2:00PM - 5:00PM

Documentation and Regulatory Writing [PQA-MRA102T]

Marks: 50 **Duration: 180 mins.**

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1)	List the items reported in the inspection report as per WHO GMP.	(5)
2)	Explain types of audit, preparation and conducting audit of manufacturing facilities.	(5)
3)	Write a note on ISO 13485	(5)
4)	What are the steps involved in CAPA in a pharmaceutical industry.	(5)
5)	Write a note on SUPAC for immediate release products and modified release for change in batch size and manufacturing site.	(5)
6)	What is exploratory product development brief? Explain	(5)
7)	What documents are required to be submitted for the Import and Registration of the bulk drug(s) and finished product(s) in India as per CDSCO?	(5)
8)	List the various dossiers submitted to USFDA during each stage of drug development and explain their content in brief.	(5)

Answer the following with specific answers (2 marks x 5 = 10 marks)

9)	Draw the Process Flow for Multiple Site Auditing as per GHTF study group 4 guidelines.	(2)
A)		
B)	What is Establishment Inspection Report? Give any two examples for commonly found cGMP violation?	(2)

C)	What is the general protocol followed by the FDA during a voluntary recall?	(2)
D)	List the types of DMF as per USFDA.	(2)
E)	List the advantages of eCTD.	(2)

-----End-----