Question Paper

Exam Date & Time: 07-May-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL REGULATORY AFFAIRS)
DATE: 07/05/2018
TIME: 02:00 PM - 5:00 PM

Regulatory Aspects of Medical Devices [PQA-MRA203T]

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

a

Answer all the questions.

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

1)	Enlist the general essential principles for safety and performance applicable to all medical devices including IVD medical devices as per GHTF guidelines.	(5)
2)	What are the exemption rules for not reporting the Adverse event with examples as per GHTF guidance document?	(5)
3)	Mention in detail the contents of STED document for IVDs as mentioned in GHTF	(5)
4)	Classify medical software as per IMDRF with appropriate examples.	(5)
5)	List ASEAN countries and name the regulatory bodies and acts governing Medical devices in each of them.	(5)
6)	Classify SaMD on basis of risk in the information provided by SaMD to decide on treatment and write in brief the categorization principles of Software as Medical device (SaMD).	(5)
7)	Write an note on CE marking as per EU directives.	(5)
8)	Write the active medical devices approval process as per EU.	(5)

b

Answer all the questions.

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

9)		(2)

A)	Mention the adverse event reporting timeline for medical devices as per ASEAN directives.	
B)	Define medical devices and IVDs with examples.	(2)
C)	Explain the types of 510(k) Submissions as per USFDA.	(2)
D)	Write a short note on Medical device approval procedure in Singapore.	(2)
E)	Classify non-invasive medical devices based on risk and intended use with suitable example.	(2)

-----End-----