Question Paper

Exam Date & Time: 06-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical Regulatory Affairs
MPharm Semester II End-Semester Theory Examination- May 2019
Date : 06/05/2019

Regulatory Aspects of Medical Devices [PQA-MRA203T]

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

SECTION - A

Answer all the questions.

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

1) What is CE marking? Describe its certification processing routes for class I and class III medical devices (10)

2) Explain the rules and classify non- invasive Medical devices intended for the following with examples (10)
a. Contact with injured skin
b. All types of non-invasive devices with or without contact to the patient

3) Explain the different types of Adverse Event reporting systems with examples in China under CFDA (10)

4) Classify medical devices and explain in detail the medical device reporting system under USFDA. (10)

5) Classify Software as a Medical Device (SaMD) with examples and mention the risk management plan to be undertaken in case of modification in algorithm affecting the diagnosis or therapy delivered. (10)

SECTION - B

Answer all the questions.

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

6) Explain invasive devices per council directive 90/385/EEC (5)

7) Draw a flow chart on evaluation and validation process of medical device software. (5)

8) Explain the phases of life cycle of x - ray machine as a medical device. (5)

9) Mention the risk management steps to be undertaken in the following case. (5)
The medical device had an extracorporeal infusion device with multiple joints in which cyclohexanone and methylene chloride were used as welding agent. Recent changes to the welding

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