Exam Date & Time: 18-Jul-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations. July 2022

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) Mention in detail the contents of STED document for IVDs as mentioned in GHTF. (10)

2) a. Write in detail the stages of clinical evaluation of medical device GHTF. (5Marks)
b. Classify SaMD on state of healthcare condition against information provided by SaMD to decide on health and write in brief the categorization principles of Software as medical device (SaMD) (5Marks) (10)

3) Analyse the data requirements of a 510k submission of USFDA and prepare a checklist for the same. (10)

4) What is CE marking? Explain the procedure for certification of class IIb and class III medical devices. (10)

5) Compare Post marketing surveillance procedure followed in China, Japan and ASEAN countries.. (10)

SECTION - B

Answer all the questions.

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

6) Enlist and explain the elements to be submitted for "conformity assessment" of both medical devices and IVDs as per GHTF. (5)

7) Explain the phases of life span of lung ventilator as a medical device. (5)

8) Mention the risk management plan to be undertaken in the following case:
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 process prompted concerns about safety during clinical use. While these solvents do an excellent job of bonding plastic materials, concerns about potential migration of the solvents during clinical use was very real. More than 35 welded joints had been identified in the product, which created a significant surface area from which the solvents might possibly leach into circulating blood. An additional concern was that the blood would circulate through the device multiple times during its typical two-hour use. (5)

9) Provide a classification for medical devices based on their risk. What are the regulatory guidance, manufacturers of class III medical devices distributed in the US must comply? (5)

10) Enlist the post-marketing requirements for medical devices as per EU regulations. (5)

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