Exam Date & Time: 11-Sep-2021 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

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) Define and enlist the general principles for safety and performance applicable to all medical devices and IVDs. (10)

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

3) Analyse the scope of FDA guideline 21CFR part 820 (Quality System regulations of Medical Devices). Discuss in detail subpart G. (10)

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

5) Prepare an "Adverse Event" case report on the following incident. A 64-year-old woman who died in a critical care unit after approximately 10 minutes of plasma exchange (PE) therapy using an apheresis machine for hemofiltration. She was to undergo PE with human albumin solution (HAS) over the course of a 60-minute treatment, with 2 L of plasma to be removed and replaced with 1.5 L of HAS. The patient had a central venous (CV) pressure cannula inserted in the right jugular vein for pressure monitoring, but it was not clear whether this catheter was used upon her admission to the intensive care unit for the PE therapy. During treatment, segments of air bubbles were seen in the venous PE line that was returning blood to the patient by the treating physician and by another physician: this air was seen entering the patient. About two minutes later, she went into respiratory arrest, and cardiopulmonary resuscitation (CPR) was initiated. During CPR, air was reportedly again seen in the venous blood line. Despite the resuscitation attempts, the patient died. Post-mortem examination indicated that the patient died of a fatal venous air embolus, probably of a volume greater than 250 ml. Air was determined to be in the brachiocephalic veins, superior vena cava, inferior vena cava, and the right ventricle. At the time of the treatment, the patient was in a semireclining position with the back of the bed raised to about 40° (10)

SECTION - B

Answer all the questions.

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

6) Draw a decision tree to illustrate the rules to classify non-invasive devices. (5)

7) Compare in brief the elements of STED and Common Submission Dossier Template(CSDT) for medical devices. (5)

8) Write in detail the stages of clinical evaluation of medical device GHTF. (5)

9) Briefly discuss the regulatory classification and approval process of medical devices as per USFDA. (5)

10) Enlist the post-marketing requirements for In-vitro diagnostics as per EU regulations. (5)

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