Question Paper

Exam Date & Time: 16-May-2023 (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 [PRM-MRA203T -S3]

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

SECTION - A

Answer all the questions.

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

1)	A. Explain and compare the relation between Global medical device nomenclature system and Unique device identification systems (5 Marks) B. Enlist the general essential principles for safety and performance applicable to all medical devices including IVD medical devices (5 Marks)	(10)
2)	A. Mention the exemption rules for not reporting the Adverse Event with examples as per GHTF guidelines. (5 Marks) B. Explain the stages of clinical evaluation of breast implants as per GHTF guidelines. (5 Marks)	(10)
3)	Define and mention the labelling requirements for immediate container, inserts and outer packing of IVDs as per 21 CFR 809.3 and prepare a label for a reagent kit.	(10)
4)	Prepare a STED application for lung ventilator as per EU regulations.	(10)
5)	Analyse and compare the post marketing surveillance (PMS) procedure followed in Japan and ASEAN countries.	(10)

SECTION - B

Answer all the questions.

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

6)	Explain the process of risk management framework of medical devices.	(5)
7)	Mention the conditions where the manufacturer of a medical device is requested for re-evaluation of final product by the competent authority.	(5)
8)	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. Postmortem 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°.	(5)
9)	Analyse and compare the conditions for a medical device manufacturer to attain authorization under	(5)

various types of 510(k) applications in US

10) Explain in vitro diagnostics devices as per EU regulations. (5)

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