Reg.No.:												

VIVEKANANDHA COLLEGE OF ENGINEERING FOR WOMEN
[AUTONOMOUS INSTITUTION AFFILIATED TO ANNA UNIVERSITY, CHENNAI]
Elayampalayam – 637 205, Tiruchengode, Namakkal Dt., Tamil Nadu.

Question Paper Code: 12003

B.E. / B.Tech. DEGREE END-SEMESTER EXAMINATIONS – MAY / JUNE 2024
Eighth Semester
Biomedical Engineering
U19BME37 – MEDICAL DEVICE REGULATIONS
(Regulation 2019)

Time: Three Hours Maximum: 100 Marks

Answer ALL the questions

Knowledge Levels (KL)	K1 – Remembering	K3 – Applying	K5 - Evaluating
	K2 – Understanding	K4 – Analyzing	K6 - Creating

PART – A

(10 x 2 = 20 Marks)

Q.No.	Questions	Marks	KL	CO
1.	List out the roles of Regulatory Affairs team in the Product development stages.	2	K1	CO1
2.	Identify an example of a class II medical device and give it uses.	2	K3	CO1
3.	Mention two benefits of implementing ISO 13485:2016 in medical device manufacturing.	2	K1	CO2
4.	State the importance of risk management in the context of ISO.	2	K2	CO2
5.	Name one regulatory authority in the USA responsible for overseeing compliance with IEC standards, and one in the EU.	2	K2	CO3
6.	How does IEC standard harmonization benefit companies operating in both the USA and the EU?	2	K2	CO3
7.	Compare FDA Law and FDA Regulations.	2	K2	CO4
8.	State the role of Central Standard Drug Control Organization (CSDCO) in the regulation of pharamaceuticals in india.	2	K2	CO4
9.	Why are clinical trials important in developing new drugs?	2	K2	CO5
10.	Identify the significance of post-market surveillance.	2	K2	CO5

PART – B

(5 x 13 = 65 Marks)

Q.No.		Questions	Marks	KL	CO
11.	a)	What is labeling? Justify the necessity of it. Elaborate the elements, risk management and clinical evaluation of labeling for medical devices.	13	K4	CO1
		(OR)			
	b)	How to categorize the medical devices? Draw the flowchart and explain the classification of medical devices.	13	K4	CO1
12.	a)	Draw the schematic essence of a Quality Management System (QMS) and describe its requirements for the regulatory approval of medical devices.	13	K3	CO2
		(OR)			
	b)	With a flow diagram, Illustrate the ISO 14971 Risk management framework analysis and its elements.	13	K3	CO2
13.	a)	Describe the key principles of Good Submission Practice (GSuP). Also elucidate the preparation and submission process of application dossiers?	13	K3	CO3
		(OR)			
	b)	Evaluate the impact of IEC standards on international trade between the USA and the EU. Consider factors such as market access and compliance costs.	13	K5	CO3
14.	a)	Explain the importance of technical materials and labeling in the context of medical devices. Discuss how accurate and comprehensive labeling can contribute to pahent safety.	13	K5	CO4
		(OR)			
	b)	Describe the statutory and other functions undertaken by DGGI, Central Government and FDA, State Government Combination. Also Represent the points in the guidance documents.	13	K4	CO4
15.	a)	Explain the process involved in preclinical and clinical trials for medical devices in India.	13	K3	CO5
		(OR)			
	b)	Discuss in detail about the Digital health regulations: Connected care, intelligent design control, reducing design time and cost.	13	K3	CO5

PART – C

(1 x 15 = 15 Marks)

Q.No.		Questions	Marks	KL	CO
16.	a)	Evaluate the effectiveness of post-market surveillance mechanism in ensuring the ongoing safety & performance of medical devices. Discuss the importance of adverse event reporting & post-market clinical follow-up.	15	K3	CO4
		(OR)			
	b)	Explain about the Digital health regulation that focuses on the product life cycle and its five key areas to achieve design excellence maturity.	15	K4	CO5