Name: Enrolment No:	

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES

End Semester Examination, May 2022

Course: Perspective in Clinical Evaluation **Semester: II**

Program: M Sc. Clinical Research **Time: 03 hrs.**

Course Code: HSCR7009 **Max. Marks: 100**

Instructions: All the sections are compulsory.

SECTION A

S. No.	CO	MCQ's /Fill in the blanks/ T&F (1.5 marks each)	Marks (30)
1.	**CO1**	……. is the assessment and analysis of clinical data.	**1.5**
2.	**CO1**	What is technical file ?	**1.5**
3.	**CO1**	Literature and clinical data are the fundamentals of clinical evaluation. True /False Justify the statement.	**1.5**
4.	**CO2**	Literature including in the data for Clinical Evaluation outcome refers to a) Device performance b) Device safety c) Device compatibility d) Device comparability	**1.5**
5.	**CO2**	Before a medical equipment is released onto the market, the manufacturer must demonstrate the foreseeable risk and any adverse outcomes. True/False Justify the statement.	**1.5**
6.	**CO2**	Who is/are the regulator/s of Clinical Evaluation Report (CER) ? a) Manufacturer/Sponsor b) Competent authorities c)Notified bodies d) b and c both	**1.5**
7.	**CO2**	Design examination of dossier done by a) Notified body b) Sponsor c) Regulatory bodies d) Investigators	**1.5**
8.	**CO3**	Title 21 of Code of Federal Regulation (CFR) is reserved for……	**1.5**

9.	**CO3**	The design, manufacture, packaging, labeling, storage, installation, and servicing of all finished medical devices intended for human use governed by part ……..under CFR ……..	**1.5**
10.	**CO3**	If you have a medical device company operating in the US market…… Part of Food and Drug Administration (FDA) regulation you need to be follow and compliant with it.	**1.5**
11.	**CO3**	Design control is applicable to all class of devices. True/False Justify your comment.	**1.5**
12.	**CO3**	Differentiate between ISO 13485 and 21 CFR 820.	**1.5**
13.	**CO3**	All medical device is considering as a drug under the rule……..	**1.5**
14.	**CO3**	Quality and Performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1945. True /False	**1.5**
15.	**CO4**	Post market surveillance falls under …….part of CFR.	**1.5**
16.	CO4	MDCG (Medical Device Co-ordination group) guidelines is for a) Manufacturer b) notified body c) Both a and b d) None of the above	**1.5**
17.	**CO4**	In India Periodic Safety Update Report (PSUR) submitted under schedule ……..	**1.5**
18.	**CO4**	Post Market Clinical Followup (PMCF) activity includes a) Gathering of clinical experience b) Feedback from users c) Screening of scientific literature d) All of the above	**1.5**
19.	**CO4**	The elements of a PMCF study should include a) Clearly stated objective b) Scientifically sound study design c) Implementation of study plan d) All of the above	**1.5**
20.	**CO4**	Clinical equivalence means physical, chemical, biological equivalence of medical devices. True/False	**1.5**

SECTION B (5 marks each question)			
Q	**CO**	Short Answer Type Question (5 marks each). Word limit (100-120)	**Marks (20)**
1.	**CO1**	A Clinical Evaluation Report (CER) is the conclusion of a clinical evaluation of medical device. A CER is made up of evaluated clinical data either from a clinical examination of device or the results of other studies on devices that are substantially equivalent to yours. The CER certifies that your technology accomplishes its goal while causing no additional danger to users or patients. Answer the following questions: a) Who writes such evaluation report ? b) Write in details about the guidelines related to it.	**(1+4)**
2.	**CO2**	Write a short note on notified bodies.	**5**
3.	**CO3**	Discuss about the Clinical Evaluation throughout the Product Lifecycle.	**2+3**
4.	**CO4**	Explain the procedure of PMCF study design.	**5**
SECTION C 30 marks			
Q	**CO**	**Two case studies 15 marks each subsections**	**Marks**
1	**CO1**	Suppose a manufacturer (XYZ) claiming that the device in question is a modification of a device. As the device is already available in the market, manufacturer need to performed some equivalence studies. If the device equivalence is same as to a competitor device in the market and the manufacturer is also claimed the same, in this condition the manufacturer needs to provide conformity assessment report to the concern body. The manufacturer already done a procedure of contract between the two manufacturers that demonstrates that the second manufacturer (XYZ) has continuous full access to the technical documentation of the proposed equivalent device. You are working in XYZ company and company is asked you to fulfill the requirement of essential guidelines. Read the above paragraph and answer the following questions a) Mentioned the equivalence studies that manufacturer need to fulfilled. b) On behalf of manufacturer where you submit assessment report for claiming equivalence to a competitor device ? c)Discuss all the essential guidelines to fulfill the requirement.	**15 (2+3+10)**
2	**CO2**	a) Develop a suitable format of CER. Being a clinical/medical writer how you can write a CER.	**15 (5+10)**

		b) Discuss about the essentials of such report.	
SECTION D 20 marks			
Q	**CO**	Long Answer Type Questions. 10 marks each Word limit 200-250	**Marks (20)**
1	**CO3**	The Central Government of India notified (April 1, 2020) that all medical devices sold in the country must be treated as drugs under the Drugs and Cosmetics Act. This means that, for quality control and pricing monitoring, all medical devices will be regulated by the government as pharmaceuticals. Read the paragraph and answer the following: a) Name the regulatory body under the Central Government who drafting such guidelines. b) Justify your thought related to such decision of Indian Government. c) What are the essential principles for safety and performance of medical device guidelines ?	**(2+2+6)**
2	**CO4**	Discuss the regulatory requirements and format of Post Market Clinical Followup (PMCF).	**10 (5+5)**