Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, May 2023

Course: Regulatory Affairs **Semester: VI**
Program: B.Sc. (Clinical Research) **Duration: 3 Hours**
Course Code: HSCC3011 **Max. Marks: 100**
Instructions: No additional material like graph paper, log table, *etc*. is allowed for this examination.

S. No.	Section A Short answer questions/ MCQ/T&F (20 Q x 1.5 M = 30 Marks)	Marks	COs
Q 1	Select the responsibility/s of RA personnel a) To undertake stability studies of the drug products b) To supervise the production of the formulation c) Work with federal, state and local governing agencies to get the approval for drug d) To analyze the content of the active ingredient in the formulation	1.5	CO1
Q 2	Agencia Nacional de Vigiloncia Sanitaria (ANVISA) is the regulatory agency of a) Switzerland b) Japan c) Brazil d) Germany	1.5	CO1
Q 3	FDA issued Tamper-resistant Packaging Regulations in a) 1982 b) 1992 c) 1971 d) 1947	1.5	CO1
Q 4	The Drug Amendments Act of 1962 was passed by Congress requiring the FDA to approve all a) New drug applications (NDA) b) Abbreviated new drug applications (ANDA) c) Both a and b d) None of the above	1.5	CO1
Q 5	Write any two advantages of electronic common technical document.	1.5	CO1
Q 6	Diethylene glycol poisoning following the use of a sulfanilamide elixir reported in a) 1937 b) 1947 c) 1973	1.5	CO1

	d) 1974		
Q 7	List of approved drugs and their associated IPR is available in a) Pink book b) Orange book c) Red book d) Black book	**1.5**	**CO1**
Q 8	Which of the following is regulatory authority of Australia a) Pharmaceutical and Medical Devices Agency b) Therapeutic Goods Administration c) Medicines and Healthcare Products Regulatory Agency d) Central Drug Standard Control Organization	**1.5**	**CO2**
Q 9	In Europe, variations are classified as Type-I A for ….....change a) Minor b) Major c) Moderate d) Relative	**1.5**	**CO2**
Q 10	What are the activities that need to be conducted by the sponsor before submitting an IND application?	**1.5**	**CO2**
Q 11	Name any TWO unfortunate events that lead to the development of new drug regulations.	**1.5**	**CO2**
Q 12	Enlist the types of new products regulated by FDA/CDER.	**1.5**	**CO2**
Q 13	Enlist various stages of drug development.	**1.5**	**CO2**
Q 14	Electronic common technical document (eCTD) is divided into how many modules?	**1.5**	**CO2**
Q 15	Which of the following is an International regulatory authority for drug regulation a) CDSCO b) US-FDA c) WHO d) EMA	**1.5**	**CO2**
Q 16	What are the responsibilities of a regulatory affair professional?	**1.5**	**CO3**
Q 17	The initiation of ICH took place with representatives of regulatory agencies of..... to discuss the wider implications and terms of reference. a) Japan, Australia, US b) US, Europe, India c) US, Europe, Japan d) Europe, Australia, US	**1.5**	**CO3**
Q 18	The objective of FDA- India office is a) To ensure the safety, quality, and effectiveness of medical products and food produced in India for export to the United States. b) Approval of medical products for marketing in India c) Import of drug in India for test and examination	**1.5**	**CO3**

	d) Manufacture of drugs in USA for the purpose of export to India		
Q 19	CFR stands for a) Code of Federal Regulations b) Centre of Federal Regulations c) Code of Federal Register d) Centre of Federal Regulator	**1.5**	**CO3**
Q 20	Central Drug Standard Control Organization (CDSCO) is the regulatory agency of which country?	**1.5**	**CO3**
Section B (4 Q x 5 M = 20 Marks)			
Q 1	Enlist various documents for regulatory writers. Discuss core expertise of a regulatory writer.	**2 + 3**	**CO1**
Q 2	Discuss any two unfortunate events and their impact on historical revolutions of global drug regulation system.	**5**	**CO2**
Q 3	State about the role of a regulatory affair professional.	**5**	**CO4**
Q 4	What is an Institutional Review Board (IRB)? What are the responsibilities of IRB?	**2 + 3**	**CO4**
Section C (2 Q x 15 M = 30 Marks)			
Q 1	(A) Explain the process of regulation and registration for biosimilar drugs. (B) Explain clinical data validation. Discuss eight characteristics of clinical data validation.	**7.5 + 7.5**	**CO3**
Q 2	(A) Write a note on medical device regulation in India. (B) Discuss various application of quality system regulation in medical device design and manufacturing.	**5 + 10**	**CO4**
Section D (2 Q x 10 M = 20 Marks)			
Q 1	What is the role of US Food and Drug Administration (US FDA) in pharmaceutical regulation? Discuss emerging product categories in the regulation of drugs.	**5 + 5**	**CO1**
Q 2	Define electronic common technical document (eCTD). Explain different modules in an eCTD.	**2 + 8**	**CO2**