Name: **Enrolment No:**	

UPES

End Semester Examination, May 2025

Course: Regulatory Affairs — **Semester : VI**

Program: B.Sc. Clinical Research — **Duration : 3 Hours**

Course Code: HSCC3011 — **Max. Marks: 100**

Instructions:: Read question paper carefully. Attempt all sections.

S. No.	Section A (20Qx1.5M= 30 Marks)	Marks	COs
1.	Define regulatory affairs.	1.5	CO1
2.	Who are stakeholders?	1.5	CO1
3.	_____ modules are there in CTD.	1.5	CO1
4.	Write the full form of ICH and mention founder countries.	1.5	CO1
5.	Discuss chapter VI of European Medical Device Regulations	1.5	CO2
6.	____ is the regulatory agency of India	1.5	CO2
7.	List any three differences between IND and NDA.	1.5	CO2
8.	Essential qualities in regulatory affair professional are ____.	1.5	CO2
9	Medical devices are classified as_____.	1.5	CO3
10.	Name any three characteristics of clinical data validation.	1.5	CO3
11.	What is the purpose of European Medical Device Regulations?	1.5	CO3
12.	Write the goals of NDA.	1.5	CO3
13.	Write the full form of the following ICH, MAA, DMF.	1.5	CO4
14.	List of regulatory authorities of Europe, Canada and UK.	1.5	CO4

15.	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	CO4
16.	In Europe, variations are classified as Type-I A for ….....change a) Minor b) Major c) Moderate d) Relative	1.5	CO4
17.	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	CO5
18.	Give a difference between MDD and MDR.	1.5	CO5
19.	State the importance of an effective SOP.	1.5	CO5
20.	State needs of regulatory affairs.	1.5	CO5
Section B (4Qx5M=20 Marks)			
1.	Short note on requirements for new drug application.	5	CO1
2.	What are the regulatory barriers affecting drug lag in developing economies'?	5	CO2
3.	Explain the process of regulation and registration for biosimilar drugs.	5	CO3
4.	Discuss in brief eCTD.	5	CO4
Section C (2Qx15M=30 Marks)			
1.	Discuss the challenges in clinical trial design optimization? Discuss with a case study.	15	CO2
2.	Write a note on approval of medical devices in USA.	15	CO5
Section D (2Qx10M=20 Marks)			
1	Give a detail procedure involved in the new drug registration process in India.	10	CO3
2.	Discuss the regulatory requirements for data validation and auditing?	10	CO2