Name: **Enrolment No:**	

UPES

End Semester Examination, May 2024

Course: Regulatory Affairs | **Semester: VI**
Program: BSc-Clinical Research | **Duration: 3 Hours**
Course Code: HSCC3011 | **Max. Marks: 100**

Instructions: Attempt all sections.

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	Cos
Q 1	Phase I of Clinical Trial involves testing the drug to assess its ----- and -----.	**1.5**	**CO1**
Q 2	Define Screening INDA.	**1.5**	**CO 1**
Q 3	Within how many days FDA conduct pre-liminary review of New Drug Application?	**1.5**	**CO 1**
Q 4	State the purpose of Phase III in the clinical trial process.	**1.5**	**CO 1**
Q 5	Describe Emergency Use Authorization (EAU).	**1.5**	**CO 2**
Q 6	Write the consequence of Great Quinine Fraud.	**1.5**	**CO 1**
Q 7	Mention two regulated and two semi-regulated market.	**1.5**	**CO 2**
Q 8	Define drug discovery.	**1.5**	**CO 1**
Q 9	Write the nature of drug target in human body.	**1.5**	**CO 2**
Q 10	Write the meaning of the term ‘Approvable’ for a NDA.	**1.5**	**CO 2**
Q 11	Define unblinded and uncontrolled study.	**1.5**	**CO 2**
Q 12	Elaborate investigator IND.	**1.5**	**CO 1**
Q 13	Enlist Class I medical device.	**1.5**	**CO 1**
Q 14	Write the objective of Phase I vaccine clinical trial.	**1.5**	**CO 1**
Q 15	Describe the regulation of pharma industry by ICH across the world.	**1.5**	**CO 1**
Q 16	Write the objective of Pivotal study during medical device trials.	**1.5**	**CO 2**
Q 17	Mention the number of patients taken during pilot study of medical device.	**1.5**	**CO 1**
Q 18	Mention the name of regulatory agencies who proposed the eCTD.	**1.5**	**CO 1**
Q 19	Differentiate between Approvable and Approval status of NDA.	**1.5**	**CO 1**

Q 20	Write the goals of NDA.	**1.5**	**CO 1**
Section B (4Qx5M=20 Marks)			
Q 1	Summarize the methodologies are utilized globally for monitoring vaccine safety after licensure.	**5**	**CO 2**
Q 2	Provide insights into the collection of post-market data for biosimilars.	**5**	**CO 2**
Q 3	Write a note on FDA regulation process for the development of OTC product .	**5**	**CO 2**
Q 4	Discuss the global impact of electronic common technical document (eCTD) submission.	**5**	**CO 3**
Section C (2Qx15M=30 Marks)			
Q 1	Write a note on followings in terms of drug discovery: a) Selection of target b) Search for candidate c) Preclinical study d) Clinical Study **OR** Write a note on accelerated vaccine development during COVID-19 including following topics: a) Preclinical and clinical development b) Regulatory approval for Emergency Use Authorization c) Post-Licensure Vaccine Safety Monitoring	**15**	**CO 3**
Q 2	Write a note on Medical Device Classification and Regulatory Pathways including following topics: a) Explanation of medical device classification (Class I, II, III) b) Different regulatory pathways for medical device approval	**15**	**CO 4**
Section D (2Qx10M=20 Marks)			
Q 1	Detail the procedure involved in the approval of a new drug application.	**10**	**CO 3**
Q 2	Write in detail about the various data requirements for clinical trial application for similar biologics.	**10**	**CO 3**