GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Bachelor of Science in Clinical Nutrition and Dietetics
Mid Term Examination - May 2024

Duration : 90 Minutes
Max Marks : 50

Sem IV - Q1UF420T - Regulatory Affairs

General Instructions
Answer to the specific question asked
Draw neat, labelled diagrams wherever necessary
Approved data hand books are allowed subject to verification by the Invigilator

1)	Explain the monitoring process in clinical research	K2	(2)
2)	Define the Case report form.	K1	(3)
3)	Differentiate between serious adverse event and adverse event.	K2	(4)
4)	Explain the rhe role of regulatory bodies in India	K2	(6)
5)	Illustrate the phase 3 of clinical studies.	K3	(6)
6)	Illustrate the role of Principal Investigator	K3	(9)
7)	Analyze of Sulphanilamide disaster in detail.	K4	(8)
8)	Analyze the role of sponsors in clinical trials? How quality is ensured while conducting clinical trials.	K4	(12)

OR

	Analyze the code of federal regulations (CFR) and define 21 CFR Part 11, Part 50 and part 56.	K4	(12)