GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Master of Science Clinical Research
Mid Term Examination - May 2024

Duration : 90 Minutes
Max Marks : 50

Sem II - Q1PN204T - Global Regulation

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 CFR (Code of federal regulation).	K2	(2)
2)	Define the Clinical research protocol.	K1	(3)
3)	Explain the SAE and AE .	K2	(4)
4)	Explain the evolution of regulatory bodies in clinical trials.	K2	(6)
5)	Illustrate the compensation to patients for clinical trial related injuries.	K3	(6)
6)	Illustrate the ICH-GCP Principles.	K3	(9)
7)	Analyze essential documents at the termination of the trial.	K4	(8)
8)	Analyze the essential documents at the end of the research in clinical trials.	K4	(12)

OR

	Analyze the responsibility of PMDA in Japan.	K4	(12)