GALGOTIAS UNIVERSITY

ADMISSION NUMBER

School of Biomedical Science

Bachelor of Science in Clinical Nutrition and Dietetics
Semester End Examination - Jun 2024

Duration : 180 Minutes
Max Marks : 100

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)	Define the Audit process as per ICH GCP E6.	K1(2)
2)	Explain the ICH GCP and indian GCP.	K2(4)
3)	Explain the bioavailability (BA) Trials.	K2(6)
4)	Illustrate the documents retrieval and archival process.	K3(9)
5)	Illustrate the Information exchange process during ICF Process.	K3(9)
6)	Examine the components of investigator brochure.	K5(10)
7)	Analyze the NDCT 2019 implementation and India's regulatory evolution.	K4(12)
8)	Examine the Points need to be explained as per ICF information.	K5(15)
9)	Examine the US food and Drug administration (FDA).	K5(15)
10)	Elaborate the Sponsor responsibility for maintaining the integrity of phase I and Phase II clinical trial.	K6(18)