School of Basic and Applied Sciences

BioScience

ETE - Jun 2023

Time : 3 Hours **Marks : 50**

Sem II - MBACRT2005 - Global Regulation

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

1.	Define monitoring in clinical research.	K1 CO3	(2)
2.	Describe Quality assurance.	K2 CO5	(2)
3.	Define serious adverse event.	K2 CO2	(2)
4.	Define adverse drug reaction.	K1 CO1	(2)
5.	Define Inspection in clinical research.	K2 CO4	(2)
6.	Describe lead identification.	K4 CO6	(6)
7.	Express the medical devices classification in clinical research industry.	K3 CO1	(5)
8.	Demonstrate the process of validation and process of verification of medical device in clinical trials.	K4 CO2	(5)
9.	Express the quality risk management of medical devices.	K4 CO5	(8)
10.	Express MHRA alongwith PMDA.	K3 CO3	(8)
11.	Evaluate IND submission of UK.	K4 CO4	(8)