Name: Enrolment No:	

UPES

End Semester Examination, December 2024

Course: GMP and GLP **Semester:3rd**

Program: BTech BIOMEDICAL ENGINEERING and BIOTECHNOLOGY

Duration: 3 Hours

Course Code: HSBE4025 **Max. Marks: 100**

Instructions: Attempt all questions

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Which regulatory guideline focuses on stability testing for drug products? a) ICH Q1A b) ICH Q8 c) FDA Part 11 d) GMP Annex 11	**1.5**	**CO1**
Q 2	In GMP, which document provides details of the manufacturing process for a product? a) Master Batch Record b) Risk Management Report c) Quality Manual d) Site Master File	**1.5**	**CO1**
Q 3	Which authority oversees drug approval in Europe? a) Food and Drug Administration (FDA) b) European Medicines Agency (EMA) c) World Health Organization (WHO) d) Medicines and Healthcare products Regulatory Agency (MHRA)	**1.5**	**CO1**
Q 4	Which phase of clinical trials is primarily concerned with determining a drug's efficacy? a) Phase I b) Phase II c) Phase III d) Phase IV	**1.5**	**CO2**
Q 5	Which term describes practices to maintain equipment cleanliness in GMP facilities? a) Sterilization	**1.5**	**CO2**

	b) Calibration c) Quality Control d) Validation		
Q 6	In QBD, "Critical Quality Attributes" refer to: a) Essential product characteristics b) Operational guidelines c) Marketing attributes d) Employee responsibilities	**1.5**	**CO3**
Q 7	Which ICH guideline primarily focuses on risk management in drug development? a) Q8 b) Q9 c) Q10 d) Q1	**1.5**	**CO3**
Q 8	GMP requirements for training are outlined in: a) ICH Q9 b) WHO TRS 961 c) FDA 21 CFR Part 11 d) ISO 9001	**1.5**	**CO2**
Q 9	Which phase of drug development is primarily concerned with ensuring safety in humans? a) Preclinical studies b) Clinical Phase I c) Clinical Phase II d) Post-marketing surveillance	**1.5**	**CO2**
Q 10	In GMP, which of the following is critical for maintaining product quality? a) Automated marketing b) Facility cleanliness c) Increased production speed d) Flexible documentation	**1.5**	**CO3**
Q 11	The role of national and international regulatory authorities is to: a) Oversee research funding b) Enforce product quality and safety standards c) Create product marketing plans d) Organize training for pharmaceutical employees	**1.5**	**CO3**
Q 12	Which term describes practices to maintain equipment cleanliness in GMP facilities? a) Sterilization b) Calibration c) Quality Control d) Validation	**1.5**	**CO3**
Q 13	Quality by Design (QBD) is only used in the pharmaceutical industry. (True Or False)	**1.5**	**CO2**

Q 14	GMP regulations are consistent worldwide. (True or False)	**1.5**	**CO3**
Q 15	What is the significance of ICH Q9 in pharmaceutical manufacturing?	**1.5**	**CO2**
Q 16	Design of Experiment (DOE) is only applicable to chemical testing. (True or False)	**1.5**	**CO3**
Q 17	Define "Pharmaceutical Jurisprudence."	**1.5**	**CO2**
Q 18	GLP and GMP compliance are optional for clinical trials. (True or False)	**1.5**	**CO1**
Q 19	What is meant by “analytical method validation”?	**1.5**	**CO3**
Q 20	Name two advantages of implementing QBD in product development.	**1.5**	**CO1**
Section B **(4Qx5M=20 Marks)**			
Q 1	Discuss the role of ICH guidelines in harmonizing drug quality standards globally.	**5**	**CO2**
Q 2	Describe the significance of batch records and how they contribute to GMP compliance.	**5**	**CO2**
Q 3	List the application of Design of Experiment (DOE) in process optimization. ***(2.5 Marks)*** Give an example of how DOE helps with quality control. ***(2.5 Marks)***	**5**	**CO1**
Q 4	Explain ethical importance of GLP in preclinical research and its impact on public health.	**5**	**CO3**
Section C **(2Qx15M=30 Marks)**			
Q 1	Describe the principles of Quality by Design (QBD) and its application throughout the product lifecycle. ***(5 Marks)*** Discuss how QBD can reduce risks in product quality and contribute to regulatory compliance. ***(5 Marks)*** Include examples of QBD tools and techniques, such as DOE. ***(5 Marks)***	**15**	**CO3**
Q2	Compare and contrast Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP). ***(5 Marks)*** Describe their roles in different stages of drug development, the specific requirements of each, and their impact on ensuring drug quality and safety. ***(10 Marks)***	**15**	**CO2**
Section D **(2Qx10M=20 Marks)**			
Q 1	Discuss the role of regulatory authorities, such as the FDA and EMA, in overseeing drug safety, efficacy, and quality. ***(5 Marks)***	**10**	**CO2**

	Explain how these agencies contribute to protecting public health and the differences in their regulatory approaches, if any. ***(5 Marks)***		
Q2	Explain the purpose and process of analytical method validation in drug development. ***(5 Marks)*** Identify the essential parameters requiring validation and demonstrate how validation processes enhance quality assurance and facilitate regulatory approval. ***(5 Marks)***	**10**	**CO3**