Name: **Enrolment No:**	UPES UNIVERSITY OF TOMORROW

UPES

End Semester Examination, December 2024

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

Program: B.Tech. BIOMEDICAL & 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 of the following is *not* a component of Good Manufacturing Practice (GMP)? a) Record keeping b) Product testing c) Employee training d) Marketing strategy	**1.5**	**CO1**
Q 2	The primary goal of Quality by Design (QBD) is to: a) Increase product costs b) Improve product quality from development stages c) Reduce testing time d) Focus only on manufacturing speed	**1.5**	**CO1**
Q 3	Which organization developed the ICH guidelines? a) World Health Organization (WHO) b) Food and Drug Administration (FDA) c) International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) d) European Medicines Agency (EMA)	**1.5**	**CO1**
Q 4	What does GLP stand for? a) Good Licensing Practice b) General Laboratory Procedures c) Good Laboratory Practice d) Good Labeling Procedures	**1.5**	**CO1**
Q 5	Which statistical method is commonly used in Design of Experiment (DOE) to determine the effect of multiple factors on a process? a) Regression analysis b) Control charting	**1.5**	**CO1**

	c) ANOVA d) Quality control chart		
Q 6	In QBD, which term refers to the documented process that consistently yields a product meeting its quality attributes? a) Process Validation b) Process Control c) Quality Assurance d) Product Licensing	**1.5**	**CO2**
Q 7	Which of the following is a key aspect of ICH Guideline Q10? a) Risk-based approach b) Clinical trial design c) Marketing approval d) Patent regulations	**1.5**	**CO2**
Q 8	Who is primarily responsible for ensuring GMP compliance? a) Regulatory authorities b) Quality control team c) Production managers d) All employees	**1.5**	**CO2**
Q 9	Quality by Design (QBD) is only used in the pharmaceutical industry. (True Or False)	**1.5**	**CO3**
Q 10	Design of Experiment (DOE) helps identify optimal conditions for manufacturing processes. (True Or False)	**1.5**	**CO2**
Q 11	Good Manufacturing Practice (GMP) regulations are the same in all countries. (True Or False)	**1.5**	**CO3**
Q 12	Ethics in manufacturing includes ensuring that no shortcuts are taken to compromise product quality. (True Or False)	**1.5**	**CO3**
Q 13	GLP guidelines apply to clinical trials in humans. (True Or False)	**1.5**	**CO3**
Q 14	The ICH guidelines are mandatory for all pharmaceutical companies globally. (True Or False)	**1.5**	**CO3**
Q 15	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**	**CO1**
Q 16	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 17	Which guideline focuses on risk management for pharmaceutical quality? a) ICH Q8	**1.5**	**CO3**

	b) ICH Q9 c) ICH Q10 d) ICH E6		
Q 18	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 19	In Design of Experiment (DOE), a factorial design is used to: a) Test one factor at a time b) Test multiple factors simultaneously c) Perform simple experiments d) Minimize testing costs	**1.5**	**CO2**
Q 20	Which of the following is *not* a purpose of Quality by Design (QBD)? a) Improve process understanding b) Ensure consistent product quality c) Reduce regulatory oversight d) Enhance product development	**1.5**	**CO2**
Section B (4Qx5M=20 Marks)			
Q 1	State the main purpose of ICH guidelines in drug development.	**5**	**CO1**
Q 2	Briefly explain the concept of "Quality by Design" (QBD).	**5**	**CO2**
Q 3	List any two critical factors that GMP guidelines focus on to ensure product safety.	**5**	**CO2**
Q 4	Differentiate preclinical and clinical studies.	**5**	**CO3**
Section C (2Qx15M=30 Marks)			
Q 1	Explain the role of Quality by Design (QBD) in the development of pharmaceutical and biotech products. ***(5 Marks)*** Determine how QBD principles are applied throughout the drug development lifecycle, including the use of Design of Experiment (DOE). ***(5 Marks)*** Provide examples of how QBD and DOE help ensure consistent product quality and compliance with regulatory standards. ***(5 Marks)***	**15**	**CO3**
Q2	Summarize the importance of Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) compliance for regulatory approval of pharmaceutical products. ***(5 Marks)*** Comment on the ethical implications of these practices in the pharmaceutical industry, including how they protect public health and ensure product safety and quality. ***(5 Marks)***	**15**	**CO2**

	Include examples of GMP and GLP requirements that are critical for maintaining ethical standards. ***(5 Marks)***		
Section D **(2Qx10M=20 Marks)**			
Q 1	Describe one application of Design of Experiment (DOE) in process development.	**10**	**CO3**
Q 2	Comment on the importance of different phases of clinical trials.	**10**	**CO2**