JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

TEST-3 EXAMINATIONS- 2026

M.Tech-I/M.Sc.Semester 2th/4TH (BT)

COURSE CODE (CREDITS): 20M1WBT231/~~21MS2MB414~~ (3) MAX. MARKS: 35

COURSE NAME: QUALITY CONTROL ANALYSIS AND MANAGEMENT

COURSE INSTRUCTOR: Dr. Gopal S Bisht MAX. TIME: 2 Hour

Note: *(a) All questions are compulsory.*

(b) The candidate is allowed to make Suitable numeric assumptions wherever required for solving problems

(c) Use of calculator is not allowed

Q.No	Question	Marks
Q1	Apply the principles of the 5S Lean process to improve efficiency in a biotechnology quality control (QC) laboratory.	[4]
Q2	A clinical laboratory is monitoring serum glucose levels using a specific automated analyzer. For a control material with a target Mean of 100 mg/dL and a Standard Deviation (SD) of 4 mg/dL, the laboratory records the following consecutive daily QC values: • Day 1: 102 mg/dL • Day 2: 109 mg/dL • Day 3: 110 mg/dL a) Analyze the QC data using Westgard Rules. Identify which specific rule has been violated by Day 3 and categorize the type of error (Random vs. Systematic). b) Evaluate the clinical impact of continuing to report patient results under these conditions. Propose a comprehensive corrective action plan that a laboratory manager must implement before resuming patient testing, referencing the phases of QC mentioned in the document.	[2] [4]
Q3	a) Apply the principles of QbD in designing a robust biopharmaceutical process. b) Analyze the relationship between CQAs, CPPs, and risk management in QbD. c) Evaluate why the US FDA mandates a three-tier categorization for Critical Quality Attributes (CQAs) and discuss how the level of statistical rigor (Equivalence Testing vs. Quality-Range vs. Graphical Comparison) is determined by an attribute's clinical relevance.	[3] [3] [4]
Q4	a) 15 samples of 200 items each were drawn from the output of a process. The number of defective items in the samples are given below. Prepare a control chart for the fraction defective and comment on the state of control.	[4]

Sample No. (i)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
No. of defective (np)	12	15	10	8	19	15	17	11	13	20	10	8	9	5	8

b). Given below are the values of sample mean X and sample range of 10 samples, each of size 5. Draw the appropriate mean and range charts and comments on the state of control of the process. (For n=5, we have A_2= 0.577, D_3=0 and D_4=2.115) [3]

Sample No.	1	2	3	4	5	6	7	8	9	10
Mean	43	49	37	44	45	37	51	46	43	47
Range	5	6	5	7	7	4	8	6	4	6

Q5 A mid-sized biopharmaceutical company manufacturing a recombinant monoclonal antibody (mAb) reported a sudden increase in batch rejections over three consecutive production cycles. The failures were associated with elevated levels of host cell protein (HCP) impurities and reduced product potency during final quality control testing. The upstream process (cell culture) appeared consistent, but deviations were observed in downstream purification, particularly in the Protein A chromatography step. [3+3+2]

An internal audit revealed that a recently introduced resin batch had slightly altered binding capacity. Additionally, minor fluctuations in column packing pressure and cleaning-in-place (CIP) procedures were noted. Environmental monitoring data also showed marginal increases in bioburden levels, though still within alert limits.

The Quality Assurance (QA) team initiated a Failure Mode and Effects Analysis (FMEA) to systematically identify risks and prioritize corrective actions. Parallelly, a root cause investigation using tools such as fishbone diagrams and 5-Why analysis was conducted. Regulatory expectations under ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality System) required thorough documentation, risk mitigation, and implementation of CAPA (Corrective and Preventive Actions).

The investigation team must determine whether the failure is due to process variability, material defects, procedural gaps, or a combination of factors. The goal is to ensure product quality, patient safety, and regulatory compliance while minimizing future risks.

1. Identify and rank at least three potential failure modes in this case using FMEA principles. What criteria would you use for ranking?
2. How would you differentiate between root cause and contributing factors in this failure investigation? Apply appropriate analytical tools.
3. What CAPA strategies would you propose to address the identified risks and ensure process robustness?