CAT 2025

PUB 3112: Biotechnology Product and Formulation

Instructions: Answer all questions.

Question 1

a. Discuss how the Quality Risk Management process can help reduce quality-related failures during the development and commercialization of bioproducts. [10 marks]

b. Examine the economic potential of bioproducts in addressing Africa's current economic challenges. [10 marks]

Question 2

a. Outline the stages of the Quality Risk Management (QRM) lifecycle in a bioproduct manufacturing facility. Describe each stage from Risk Identification to Risk Review. [15 marks]

b. What are the typical acceptance criteria used during risk assessment in various processes of bioproduct manufacturing? [5 marks]

Question 3

a. Explain why recovery and purification processes are essential in the development of bioproducts. [5 marks]

b. Describe the key methods used for the recovery and purification of bioproducts, and discuss their advantages and limitations. [15 marks]

Question 4

a. Describe the Stage-Gate model for product development, highlighting the steps from discovery to product launch. [10 marks]

b. Explain how seed/angel investors and venture capitalists contribute to rescuing innovative products from failure during the critical "Valley of Death" phase in the product development cycle. [10 marks]