18BT81

USN

Eighth Semester B.E. Degree Examination, Jan./Feb. 2023
Regulatory Affairs in Biotech Industry

Time: 3 hrs.   Max. Marks: 100

Note: Answer any FIVE full questions, choosing ONE full question from each module.

Module-1

1   a. Explain the objectives and scope of GLP guidelines.   **(10 Marks)**
    b. Write a note on Retrospective validation and prospective process validation. **(10 Marks)**

OR

2   a. Write the significance of GMP in Quality Assurance.   **(10 Marks)**
    b. Define and explain the following :
        (i) IQ (Installation Qualification)   (ii) OQ (Operational Qualification)   **(10 Marks)**

Module-2

3   a. What is process validation? Explain the process validation procedure with respect to API's.
                                                                                     (10 Marks)
    b. Differentiate in detail Limits Of Detection (LOD) and Limits Of Quantification (LOQ).
                                                                                     (10 Marks)

OR

4   a. Explain in detail about the statistical process control of HPLC.   **(10 Marks)**
    b. What are the ICH guidelines pertaining to pharmaceutical quality management. **(10 Marks)**

Module-3

5   a. ISO 9000 QMS prescribes Eight Quality Management principles as a guide for forming and
        managing the system? Briefly describe 5 of them.   **(10 Marks)**
    b. Define product Realization? Add a note on its Analysis and Improvement.   **(10 Marks)**

OR

6   a. Briefly describe the Intent of the Quality Policy in an organization implementing ISO 9001.
                                                                                     (10 Marks)
    b. What do you mean by document and data control? Write a note on its implementation
        process.   **(10 Marks)**

Module-4

7   a. What are the benefits of Total Quality Management, mention atleast five?   **(10 Marks)**
    b. Is there a difference between Quality control and Quality Assurance? If yes, what is it?
                                                                                     (10 Marks)

OR

8   a. Explain the Quality Policy and objectives related to pharmaceutical industries. **(10 Marks)**
    b. Discuss on the concept of Inspection and testing with an example.   **(10 Marks)**

Module-5

9   a. Discuss on the concept of model validation and verification during the life cycle
        manufacturing process description.   **(10 Marks)**
    b. Explain with an example FMEA (Failure Mode Effects Analysis).   **(10 Marks)**

OR

10 a. Briefly explain the concept of clinical trials Quality Assurance Management. **(10 Marks)**
    b. State your point of view on solid dose manufacture principles and practices. **(10 Marks)**

* * * * *