CBCS SCHEME

USN | | | | | | | | | |

18BT81

Eighth Semester B.E. Degree Examination, Dec.2023/Jan.2024
Regulatory Affairs in Biotech Industry

Time: 3 hrs. Max. Marks: 100

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

Important Note : 1. On completing your answers, compulsorily draw diagonal cross lines on the remaining blank pages.
2. Any revealing of identification, appeal to evaluator and /or equations written eg, 42+8 = 50, will be treated as malpractice.

Module-1

1 a. What is validation? Analyse the regulatory requirement of FDA for validation in pharmaceutical industries. **(10 Marks)**

b. Critically evaluate the biopharma industrial compliance requirement as per GLP, GCP and GMP. **(10 Marks)**

OR

2 a. Differentiate between qualification and validation in biopharma industries. **(10 Marks)**

b. What are the different types of process validation according to the FDA guidelines? **(10 Marks)**

Module-2

3 a. Comprehend the validation of water purification process in the process industry. **(10 Marks)**

b. Discuss the validation of non-sterile process used in the manufacture of solid active pharmaceutical ingredient. **(10 Marks)**

OR

4 a. How validation of analytical methods used in pharma industries is done as per FDA and KH guidelines. **(10 Marks)**

b. How active pharmaceutical ingredients processed through aseptic process are validated? **(10 Marks)**

Module-3

5 a. How format of ISO 9000 changed from older version to latest version of ISO 9000 series. **(10 Marks)**

b. What are the requirements of ISO 9000 under quality system? **(10 Marks)**

OR

6 a. How both ISO 9001 and ISO14001 concern the way an organization goes about it work. **(10 Marks)**

b. What is Internal Audit Check list as per ISO 9001:1994 and ISO 9001:2000? **(10 Marks)**

Module-4

7 a. Comprehend the term:
(i) Measurement Management System (ii) Measurement Process
(iii) Quality Policy (iv) Quality objectives **(10 Marks)**

b. Explain the following terms related to QMS:
(i) Characteristics (ii) Traceability
(iii) Conformity (iv) Defect **(10 Marks)**

OR

8 a. Write short notes related to examination as defined in ISO 9000 : 2005
(i) Objective evidence
(ii) Inspection
(iii) Test
(iv) Conformation **(10 Marks)**

b. Discuss the fundamentals of quality management system as per ISO 9000. **(10 Marks)**

Module-5

9 a. How to develop a regulatory requirement of validation. **(10 Marks)**

b. Explain the V modes and life cycle model approach to validation. **(10 Marks)**

OR

10 a. Discuss the different Risk analysis techniques in Quality Management. **(10 Marks)**

b. How Regulatory Impact analysis is performed? **(10 Marks)**

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