CBCS SCHEME

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15BT82

Eighth Semester B.E. Degree Examination, Aug./Sept.2020
Regulatory Affairs in Biotech Industry

Time: 3 hrs. Max. Marks: 80

Note: i) For Regular Students: Answer any FIVE full questions irrespective of modules.
ii) For Arrear Students : 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. Define process validation. Explain about the stages of process validation. **(08 Marks)**
b. Define ISO 9000. Explain about the ISO series of standards. **(08 Marks)**

2 a. Define Process Analytical Technology [PAT]. What does FDA regulates? Explain with examples. **(08 Marks)**
b. What are IQ, OQ, PQ? Why are they required in the pharmaceutical Industry? **(08 Marks)**

Module-2

3 a. Define clean room. Write a note about the HVAC and cleaning validation. **(07 Marks)**
b. What is statistics? Discuss about the statistical process control for HPLC. **(09 Marks)**

4 a. What is active Pharmaceutical Ingredients (API's)? Explain about the Importance of API's validation. **(08 Marks)**
b. Define Limits of Quantification [LOQ]. Explain about the ICH guidelines with respect to the method of the evolution. **(08 Marks)**

Module-3

5 a. Define ISO-14001. Discuss about the Importance of ISO-14001 in Environmental Management System (EMS). **(08 Marks)**
b. Discuss about the product realization, measurement analysis and improvement. **(08 Marks)**

6 a. Explain about the preservation, delivery and control of Quality Records. **(08 Marks)**
b. Discuss about the document Requirements and Management's responsibility. **(08 Marks)**

Module-4

7 a. What is Quality Triology? Write a note about the terms relating to the Quality, Management and Quality Management Systems. **(08 Marks)**
b. Explain about the Quality system, contract review design control, document and data control. **(08 Marks)**

8 a. Write a note on:
i) Internal Quality Audit's, Training and Servicing
ii) Process Control, Inspection and Testing. **(08 Marks)**
b. Define: i) Conformity ii) Corrective Action iii) Deviation permit iv) Defect. **(08 Marks)**

Module-5

9 a. Discuss about the Failure Mode and Effects Analysis (FMEA). **(07 Marks)**

b. What is revalidation? Explain about the liquid and cream manufacture principles and practices? **(09 Marks)**

10 a. What is pharmaceutical engineering? Write a note on Facility, Equipment design and process design in pharmaceutical engineering. **(09 Marks)**

b. Explain about the quality and continuous improvement in the biotech industry. **(07 Marks)**

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