CBCS SCHEME

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15BT82

Eighth Semester B.E. Degree Examination, July/August 2021
Regulatory Affairs in BT Industry

Time: 3 hrs. Max. Marks: 80

Note: ***Answer any FIVE full questions.***

1 a. Briefly explain the concept of process validation with the help of case study. **(08 Marks)**
b. Explain the importance of GMP in a pharmaceutical sector. **(08 Marks)**

2 a. Compare and contrast process validation and process qualification. **(08 Marks)**
b. Justify the need and use of statistical process control technique in BT industry. **(08 Marks)**

3 a. List out the steps in validating a HVAC system. **(10 Marks)**
b. Explain the validation process for Non-sterile processes. **(06 Marks)**

4 a. With a case study justify need for validating the analytical instruments. **(08 Marks)**
b. List out the steps to troubleshoot out of control systems. **(08 Marks)**

5 a. Give a brief description on ISO 9000 series of standards. **(08 Marks)**
b. Describe the managements responsibility in maintaining quality standards. **(08 Marks)**

6 a. Define Quality Management System (QMS). Give the roles and responsibilities of QMS. **(08 Marks)**
b. Describe how measurement, analysis and improvement is done to maintain the quality of products. **(08 Marks)**

7 Critically comment on:
a. Quality Assurance.
b. Quality Policy.
c. Quality Improvement.
d. Quality planning. **(16 Marks)**

8 Compare and contrast on:
a. Conformity and Non conformity.
b. Preventive action and Corrective action.
c. Final inspection and Testing Inspection.
d. Design control and Data control. **(16 Marks)**

9 a. Compare and contrast Vmodel and life cycle model to validation. **(08 Marks)**
b. Justify the need for Risk Analysis Techniques through failure mode and Effect Analysis (FMEA) in BT industry. **(08 Marks)**

10 a. List out the steps in computer system validation. Justify with case study. **(08 Marks)**
b. Explain the need of Process Analytical Technology (PAT) in pharmaceutical industry. **(08 Marks)**

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