BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI
Quality Assurance and Regulatory Affairs (PHA G532)
Comprehensive examination-2022 (Closed Book)
Total Marks: 35 M Duration: 180 Mins Date: 21/12/2022

Instructions:

- ✓ **Write correct and precise answer. No spelling mistakes. Marks will only be given to correct and well explained answer and not to partial answers.**
- ✓ **Write in clear and legible handwriting. Do not write short forms. Answer the questions in same sequence. Write the each question on a separate sheet.**

1. Explain the different points need to be mentioned in the discussion of the rationale for the development of the medicinal product as per ICH-M4E (R1) and write the objectives of ICH-E5. **4M+4M**
2. Write the definition of Audit as per European Union (EU) GMP Directive 91/356/EEC states. Explain the key points of the EU definition. Explain the business benefits of good audits. **6.5M**
3. Describe the interrelationship between QC, QA and GMP and write the objectives of Quality Management System. **3M+3M**
4. In May 2013, the US FDA withdrew approval for Wockhardt's manufacturing units in India and restricted the sale of Wockhardt's products in USA. In this context explain, 21 CFR 11.188(b) in detail. **6M**
5. Explain the vision which will be achieved by the companies after effective TQM implementation. **3M**
6. A "X" Pharmaceutical Company has started a production of tablets. For their production process, they want to establish an X bar and R chart for improvement in production process. On five different days a 25 sub-groups were collected with 6 observations in each subgroup, below are the data for the average and range of individual sub groups (Tablet weights in g).

Sub Group	X Bar	R
1	20.35	0.34
2	20.40	0.36
3	20.36	0.32
4	20.65	0.36
5	20.10	0.36
6	20.40	0.35
7	20.43	0.31
8	20.37	0.34
9	20.48	0.30
10	20.42	0.37
11	20.39	0.29
12	20.38	0.30

Sub Group	X Bar	R
13	20.40	0.33
14	20.41	0.36
15	20.45	0.34
16	20.34	0.36
17	20.36	0.37
18	20.42	0.98
19	20.66	0.38
20	20.31	0.35
21	20.39	0.38
22	20.39	0.33
23	20.40	0.32
24	20.41	3.34
25	20.40	0.30

From this data:

a) Assuming the process is in a state of control, compute the X Bar and R chart trial central line and trial control limits for the next production cycle. **[3M]**
b) Assume that the process has assignable causes. Calculate the revised limits and central line. **[2.5M]**

For Table B, refer the back side of question paper. Write answer till third decimal point without rounding it off.