BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI

Quality Assurance and Regulatory Affairs (PHA G532)

Comprehensive examination-2023 (Closed Book)

Weightage: 35 % Duration: 180 Mins Date: 11/12/2023

Instructions:

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

1. Considering you as one of the sponsors, and want to conduct a non-clinical laboratory study for the BITS123 compound having an antihypertensive activity. In this regard,
   a) What will testing facility management's role in carrying out this study? 3.5M
   b) What are the things that need to be assured by the study director while doing the study for the BITS123 compound? 2.5M

2. In May 2013, the US FDA withdrew approval for Wockhardt's manufacturing units in India and restricted the sale of Wockhardt's products in the USA. Explain 21 CFR 211.188(b) in detail. 6M

3. Describe the interrelationship between QC, QA, and GMP. 3M

4. Total Quality Management (TQM) is to provide a quality product to customers, which will, in turn, increase productivity and lower costs. With respect to this, define the different quality elements in TQM from the previous state. 4.5M

5. Explain common technical documents' background, scope, and objectives. 1M+3M+4M

6. What do you mean by a process in control? Explain in detail the advantages of "when the process will be in control." 1M+7M

7. Explain in detail the objectives/purpose of variable control charts. Write a note on the rational subgroup, selection of subgroup samples, and subgroup size. 5M+4.5M