BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI

Quality Assurance and Regulatory Affairs (PHA G532)

Comprehensive examination-2016 (Closed Book)

Total Marks: 50 M (Weightage: 30%) **Duration: 180 Mins** **Date: 13/12/2016**

Write precise answers, please do not write story.

1. Explain the term "Secondary Pharmacological Data". Comment on regulatory assessment of *in vitro* secondary pharmacology data. [1M+4M]

2. Explain the background, scope and objectives of common technical documents. Describe the organization of CTD. [6M+2.5M]

3. Explain the interrelationship between GMP/QA/QC. GMP is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. Explain some main risks involved in any pharmaceutical production. Write the different requirements for Good Manufacturing Practices. [3M+3M+3M+4.5M]

4. Explain the ISO 9000:2000 definition of quality. Write the key requirements of ISO quality management system. [2M+5M]

5. What is NGCMA? As per the part 58, explain role of Quality Assurance Unit in a GLP certified facility in carrying out preclinical studies. Explain the business benefits of good audits [1M+4M+2M]

6. Define the term 'Quality Audit' as per ISO 8402:1986. How it is different from European Union (EU) GMP Directive 91/356/EEC states. Explain the key points of quality audit. [1M+1M+2M]

7. Write the composition of quality council. Explain the duties of quality council. [1M+4M]