BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI

Quality Assurance and Regulatory Affairs (PHA G532)

Mid Semester examination-2016 (Closed Book)

Weightage: 30% **Duration: 90 Mins** **Date: 08/10/2016**

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

2. Define the Quality as per ISO9000:2000. Write the characteristics of leadership. [2M+6M]

3. What do you mean by preclinical studies and explain its objectives? How these studies help in the process of drug discovery and development? List the different toxicity studies need to be performed for new chemical entity. [3M + 2M +2M]

4. Define the term population and sample with suitable examples. When the sampling is necessary and sample represents the population is function of what? [2M+3M+2M]

5. Explain in detail the different phases of an investigation as per CFR 312.21. [4M]