Title: **QA Specialist, GCP/GLP** Department: **Quality Management**

Position Summary:

This position will be responsible for all Quality Assurance GCP activities. The primary responsibilities will be to ensure quality and compliance of clinical trials with respect to Standard Operating Procedures and applicable regulatory requirements (CDSCO, FDA, EU, ICH & country-specific, and current industry standards and practices) as well as support the non-clinical team on ensuring GLP studies are conducted in a compliant manner. This position reports to the Executive Director, Quality.

Responsibilities:

- Schedule, oversee, and perform routine and non-routine quality assurance audits to include:
  - Clinical investigator sites, animal testing sites, vendors, process, system, study project, and document reviews to assure quality assurance compliance concerning all internal procedures and regulatory guidelines.
- Provide GCP and GLP QA oversight and support to internal staff.
- Assist Clinical Ops in developing Clinical SOPs and other quality documents.
- Develop and implement detailed audit plans and yearly GCP /GLP audit schedules.
- Ensure the timely and effective follow-up of all identified or assigned quality issues.
- Assist in preparing investigational sites for regulatory inspections.
- Conduct a QA review of GCP protocols, ICFs, CSRs, and other clinical trial-specific documents.
- Conduct QA review of GLP reports.
- Schedules and/or delivers yearly GCP training for internal staff.
- Assists with GCP training of study site personnel as needed.

Minimum Qualifications & Experience:

- **Bachelor's Degree in a Pharmacy** discipline, a combination of relevant education
- Minimum **1-2 Year of experience in GCP/GLP QA** with **Global Oncology Biosimilar Clinical Trial exposure** will be preferred.
- Solid understanding of GCP, GLP and ICH clinical requirements
- Experience with both domestic and international clinical studies.
- Able to travel domestically 25% of the time.