**Clinical Operations and Oversight Manager or Senior Manager**

**Accountability:**

Country/hub leader of Clinical Operations organization that is accountable for timely, quality clinical study delivery and oversight CROs in North America. Actively partners with cross-functional stakeholders to support R&D strategy.

**Responsibility:**

* Performance management and oversight of CRO and locally accountable for execution of clinical studies
  + Perform sponsor oversight activities of CRO to ensure quality and delivery of GenScience clinical trials.
  + Ensure timely, quality communication to cross-functional teams to support clinical study execution.
  + Monitor study progress and drive local action plans & issue resolution.
  + Provide local expertise through tools or upon request.
  + Participate in external engagement activities (e.g. boost visit to the site).
* Risk mitigation and quality management
  + Proactively identify risks and develop risk mitigation strategies to ensure operational effectiveness.
  + Point for escalation for resolution of complex clinical study related issues & risks identified.
  + Oversee quality and ensure country/hub deliverables in accordance with ICH-GCP and Local Regulations.
  + Support inspection readiness, site audits and regulatory inspections, including CAPA resolution.
  + Lead local process improvement initiatives.
* Engage local cross-functional teams to maximize local support of clinical studies
  + Maintain relevant therapeutic knowledge and clinical research best practices.
  + Provide information and request support as needed.

**Requirement:**

* Bachelor’s degree & above in Biology or related field, clinical medicine would be preferred.
* At least 8 years’ experience in clinical research execution, including at least 3 years project management experience. Demonstrated successful experience in project/program management and matrix leadership.
* Knowledge in global regulatory and compliance requirements for clinical research, including but not limited to US CFR, EU CTD and ICH GCP. Awareness of local country requirement.
* Good project management skill (e.g. good planning, implementation and follow up).
* Excellent teamwork, organizational, interpersonal and problem-solving skills.