75 State Street, Suite 1400, Boston MA 02109 USA

Position Title:	Associate Director, GLP & GCP Quality
Department:	Quality
Hiring Manager:	Paul Stanley

We are a team of experts from multiple disciplines who have come together driven to bring hope and life-changing therapies to patients and their families.

Position Overview:

As the Associate Director, GLP and GCP Quality Assurance, you will report to the Astria Head of Quality. You will be responsible for conducting the GCP/GLP QA activities that range from non-clinical development, first in human clinical trials through commercial marketing authorization. You will provide QA oversight of GCP/GLP/ GCLP contract research organizations (CROs), and Investigator Sites. You will ensure that the appropriate processes, systems, and activities are in place and performed to protect the rights, safety, and welfare of our clinical patients. In this role, you will partner cross functionally, serving as the QA representative to the Research, Nonclinical Development, Clinical Operations, Translational Medicine and Safety/ Pharmacovigilance Teams. You will serve in a leadership role to identify, drive, and implement GCP/GLP process, improvements, and supporting the state of GCP/GLP compliance.

Responsibilities:

- Contribute to development, implementation, and maintenance of a phase-appropriate, risk-based clinical GLP/GCP quality management system that supports the quality and compliance of nonclinical and clinical activities in accordance with ICH Guideline E6 Good Clinical Practice (GCPs), 21 CFR part 58 Good Laboratory Practices (GLP), and other global regulatory authority requirements, and industry practices.
- Provide QA oversight to internal non-clinical, clinical and safety/ pharmacovigilance operations to ensure compliance with Astria procedures and processes.
- Identify QA and compliance related issues, implementing solutions to ensure timelines are maintained.
- Provide consultation in interpretation of regulations/guidelines, as they apply to GLP, GCP and GCLP practice, via awareness of regional regulatory requirements, and phase of study.
- Provide QA review and approval of GLP and GCP study protocols and reports, Investigator Brochures, ICFs, study plans and manuals, and regulatory submissions (i.e., IND/IMPD).
- Serve as the primary QA representative at internal cross-functional clinical trial team meetings, safety/PV meetings and program core team meetings.
- Contribute to GLP and GCP vendor selection processes.
- Oversee GLP/ GCP/ GCLP vendor qualification and vendor management activities.
- Establish and manage nonclinical and clinical audit plans/schedules in collaboration with nonclinical and clinical development teams. Participate in vendor and clinical site audits.
- Collaborate with and provide leadership for the management of vendor related performance or compliance issues.

- Support and maintain a robust training program. Develop training materials and conduct training for Astria personnel on Astria processes, procedures, global regulations and guidance documents.
- Generate nonclinical and clinical QA metrics and present at senior leadership meetings.
- Stay ahead of industry developments, forthcoming regulations, updated guidance, and best practices.
- Continue to develop as an subject matter expert for areas of responsibility.

Qualifications:

- BS/MS in biology, chemistry, life sciences or related field.
- At least 8+ years' experience in pharmaceutical / biotech / clinical research industry with significant experience in GCP/ GLP/GCLP/ environment.
- Knowledge - Strong understanding of Global GCP/GLP regulations and industry standards. Experience supporting BIMO inspections preferred.
- Organizational Skills – Demonstrated ability to effectively manage multiple responsibilities and still meet high quality and timeliness standards. Ability to operate independently and seek resources when needed. Demonstrated ability to lead and organize cross-functional team meetings.
- Problem Solving – Ability to dissect and understand a situation or problem by applying a systematic approach to identifying root causes, assessing risk and establishing appropriate risk mitigations.
- Communication and Teamwork – Ability to effectively express ideas in written and oral context; to work co-operatively with others; genuine desire to be a part of a team and contribute to organizational and team goals. Builds productive working relationships across a diverse spectrum of people.
- Adaptability & Flexibility – Ability to work effectively within a variety of situations; adapts enthusiastically to organizational change and to changes in job demands.
- Leadership- Demonstrated proactive and continuous improvement mindset. Strong alignment with Astria core values. Comfortable and adept at communicating expectations and holding others and self-accountable. Enthusiastic, forward-looking.
- Interest and ability to travel domestically and internationally.