75 State Street, Suite 1400, Boston MA 02109

Position Title:	Associate Director, Quality
Department:	Quality
Hiring Manager:	VP of Quality

Our vision is a world where science, passion, and compassion create better todays and more tomorrows.

Associate Director, Quality:
This is an exciting time to join our Quality organization at the early clinical development stage. The Associate Director, Quality will have exposure to and will provide support to the various functions across GxP. The individual will also support and contribute to the growth of the Astria quality management system and have significant interaction with both internal and external partners. Excellent communication, collaboration, organization, technical and critical thinking skills are essential for this role. This position reports into the VP of Quality.

Specific Responsibilities Include:

- Liaison with Astria non-clinical development, pharmaceutical sciences & technical operations, and clinical operations.
- Represent Quality within the Astria partner network
- Coordinate with non-clinical development for Quality review of GLP study protocols
- Provide critical review of GxP site and vendor SOPs, protocols, reports, test methods, batch records, certificates of analysis, change controls, investigation reports, and CAPA for adequacy and compliance.
- Lead quality investigations, CAPA, change controls and risk assessments.
- Ensure all work performed and documentation generated meets Astria requirements.
- Assist quality system record owners (e.g. Change Control, CAPA, Risk Assessment, investigations) with ensuring compliance to governing procedure requirements.
- Manage GxP external audit processes.
- Coordinate cross-functionally for the continued phase appropriate development of the Astria quality management system.
- Provide administrative oversight to Astria GxP document management and training management programs.
- Provide new hire, refresher, e-system, and ad hoc training to Astria GxP personnel
- Maintain quality management system performance metrics periodic management reviews.
- Help develop, track and drive compliance and performance goals.

Required background and experience:

- Bachelor of Science degree preferred. 8 plus years' experience in pharmaceutical GxP Quality
- Demonstrated experience in working in compliance with US, EU and ICH GMP requirements
- Biologics experience preferred
- Experience in supporting a clinical stage company preferred
- Demonstrated experience with electronic enterprise quality management systems (e.g. ZenQMS, Trackwise, Veeva).
- Strong interpersonal skills to effectively manage teams, communicate with peers, management, and external contacts.