



200 Clarendon Street, 17th Floor
Boston, MA 02116

Position Title: Senior Manager Quality Assurance

About AZTherapies: Extending Brain Health

AZTherapies is an advanced clinical-stage biopharmaceutical company developing novel therapies that aim to fundamentally change neurodegenerative disease progression, extending normal cognition and function and improving quality of life in the aging population. Advancing a growing pipeline of candidates to treat patients with few therapeutic options, our lead program, ALZT-OP1, is built on a multi-modal approach that recognizes neuroinflammation as a root cause of serious neurodegeneration and seeks to stop or slow the progression of disease. Our Phase 3 COGNITE trial in early Alzheimer's disease is fully enrolled, with expected study completion later this year. Following our lead program, we are advancing candidates for the treatment of amyotrophic lateral sclerosis (ALS), post-ischemic stroke cognitive impairment, and other indications. Our company is also developing a platform of Chimeric Antigen Receptor (CAR) engineered T regulatory cells (CAR-Treg) to shut down neuroinflammation and treat neurodegenerative diseases. AZTherapies is a private company headquartered in Boston, Massachusetts.

An Exciting Opportunity in a Fast-growing Organization

The Senior Manager of Quality Assurance at AZTherapies will support the implementation and continuous improvement of quality systems in compliance with US and international regulations, laws, and guidelines. Reporting to the Senior Director of Quality Assurance, the Manager will be accountable for implementing and developing quality systems that are appropriate for management and oversight of CROs, CMOs and testing laboratories, etc. and Sponsor responsibilities including, but not limited, to training, documentation, quality metrics, discrepancy, change control, CAPA and vendor management.

The position requires professionalism and discretion, the ability to multi-task while delivering high quality work, and the capability to work effectively in a rapidly changing environment. The role will interact closely with all levels of management and staff, as well as outside service providers (vendors, consultants, etc.).

Summary of role:

- Manage and continuously improve the Quality Management System.
- Support the Vendor Qualification, Auditing, Inspection preparation and Quality Agreements systems including establishing and executing the Vendor Audit Plan utilizing internal and external audit resources.
- Coordinate and support the creation of and revisions to Standard Operating Procedures (SOPs) and other controlled documentation for GxP functions.
- Develops and provides training, when appropriate, and ensures compliance with the Training system.
- Support the preparation for and hosting of regulatory agency inspections.
- Reviews and evaluates corrective/preventive actions (CAPA) including the CAPA effectiveness program.
- Establish metrics and monitor/report the status of the QMS activities.
- Work cross functionally to build processes that will drive innovation, teamwork and efficiency within the organization.
- Support Quality Operations activities, as required.
- Promote a Quality Culture.

Qualifications:

- BS degree with a minimum of 10 years of experience in Biotech or Pharma and 5+ years' experience in Quality Systems management roles. A degree in life sciences or Chemistry is beneficial.
- Ability to develop and implement appropriate GxP quality systems to ensure site compliance and Sponsor oversight responsibilities.
- Identify key quality metrics for monitoring quality system performance and management reporting.
- Experience in preparing for and supporting inspections by regulatory agencies.
- Understanding of domestic and international regulatory requirements.
- Ability to effectively prioritize and manage multiple projects and tasks.
- Possess a flexible approach to problem solving.
- A team player, who listens effectively and invites response and discussion.
- A collaborator who communicates in an open, clear, complete, timely and consistent manner.

Competencies:

- The ability to adapt and work effectively within a variety of situations; adapts to organizational priorities and changes in job demands.
- Builds productive working relationships across a diverse spectrum of departments.
- Ability to handle multiple responsibilities simultaneously and meet high quality and timeliness standards.