



Mighty Therapeutics, Inc. is an innovated biopharmaceutical company pioneering a new class of medicines that directly target mitochondrial dysfunction, improving quality of life for individuals who have long-faced limited options. Driven by a desire to help patients with unmet medical needs, our team collaborates with well-recognized institutions, physicians, and scientists to develop the next generation of therapies focusing on mitochondria dysfunction in many diseases.

Position Title: Vice President, Quality Assurance

Position Summary:

Reporting to the CEO, the Vice President, Quality Assurance, will lead the continued development and improvement of Mighty's Quality Management System (QMS). This role will oversee GxP quality activities across clinical and commercial programs and provide guidance and mentorship to a growing team of QA professionals.

Responsibilities:

- Provide leadership, direction, and enhancement of the Mighty Quality Management System (QMS).
- Maintain Quality oversight and management of GXP activities including external clinical and commercial stage CMOs, contract testing laboratories and clinical trial CROs.
- Oversee Quality activities associated with clinical trial initiation and maintenance as well as commercial launch and compliance activities.
- Create and maintain a status of Regulatory Inspection readiness for both clinical and commercial stage systems.
- Maintain a company-wide Quality culture through participation in team meetings as well as individual mentorship.
- Ensure that continuous GXP training is implemented and adapted according to regulatory compliance requirements, as well as functional department and overall company needs.
- Provide overall leadership for the Quality Assurance function.
- Develop and mentor a team of Quality professionals.

Competencies:

- Excellent verbal and written communication skills. Ability to effectively communicate Quality direction cross-functionally, based on regulations and business needs.
- Demonstrated ability to apply knowledge strategically and operationally across projects within a matrix environment with strong negotiation and facilitation skills.
- Strong organization skills with the ability to effectively multi-task and prioritize.
- Ability to flexibly adapt to changing business needs and meet timelines within a fast-paced environment.
- Self-motivated with sound judgement and problem-solving skills.
- Strong people manager with ability to achieve results through principle-based leadership.

Requirements:

123 Highland Avenue, Suite 201, Needham, MA 02494 | Phone 617-600-6888 | Fax 617-600-6884 | MightyTx.com



- Bachelor's degree in a scientific or engineering discipline.
- Minimum of 15 years pharmaceutical industry experience in Quality Assurance including experience in small molecule manufacturing in both clinical and commercial stage projects.
- Demonstrated experience building and leading QA teams.
- Experience supporting NDA approval, regulatory inspections, commercial launch, and post-approval quality activities preferred.
- Strong understanding of 21CFR, ICH, FDA and EU/UK regulatory standards /guidance documents.
- Proven track record of leadership and building relationships with internal and external Quality customers.