

**Position:** Director, R&D & Clinical Quality Assurance

**Manager:** Sr. Director, R&D and Clinical Quality Assurance

**Department:** R&D and Clinical Quality Assurance

## **JOB SUMMARY:**

The Director, Clinical Quality Assurance will be responsible for providing quality oversight for the clinical programs related to the company's ZFP and cDNA Therapeutic® products, including technology platforms for ZFP genome editing, Adeno-associated Virus (AAV) gene therapy and autologous & allogeneic CAR-Tregs.

The Director, Clinical Quality Assurance will work closely with Quality Assurance and Clinical Operations to recommend and lead the implementation of quality initiatives to ensure clinical compliance to FDA and international regulations and guidance, including Good Clinical Practices. Will lead the GCP vendor qualification and management efforts. Will be responsible for creating the clinical quality systems necessary to support the client's Phase III clinical operations goals.

## **ESSENTIAL FUNCTIONS:**

- Establishes, refines, implements, and maintains Clinical QA systems, policies and procedures for oversight of the company's internal clinical operations. Evaluate the company's readiness for Phase III clinical trials and implement the systems necessary to comply with US/EU regulatory requirements.
- Participates in clinical programs and coordinates the QA interface with Contract Clinical Research Organizations, Clinical Contract Test Organizations, and Investigator Sites.
- Leads the vendor evaluation process and vendor qualification program as it relates to Clinical Operations through on-site audits and on-going monitoring of compliance to regulations and company policies.
- Ensures regulatory compliance as it relates to clinical research through ongoing assessment of the clinical development portfolio, identification of key sites that may pose a risk to that portfolio, conducting regular site audits and triggering and monitoring corrective action as needed to ensure regulatory compliance.
- Manages the internal audit process of Clinical Operations including execution, report writing and CAPA follow-up.
- Manages Deviations related to Clinical Operations including reporting on investigations, clinical impact, and resolution to Senior Management.
- Provides advice and interpretation of regulations and guidelines.
- Participates in the review and approval of clinical trial materials such as Clinical Protocol, Pharmacy Manual, Clinical Investigator's Brochure, etc.
- Supports the organization's training program as it relates to Clinical Operations.
- Supports regulatory inspections of the company and its suppliers as needed.
- Provides Quality Assurance support for safety-related monitoring and pharmacovigilance.

- Supports the Quality Assurance Unit in other tasks necessary to maintain the Quality System.
- Participates in the implementation and deployment of electronic quality systems to support Clinical initiatives.

**EDUCATION, EXPERIENCE AND SKILLS REQUIREMENTS:**

- Minimum of a bachelor's degree in life science or equivalent
- Demonstrated in-depth experience of establishing, refining, and operating Clinical Quality Assurance related systems in the Biotechnology industry.
- 12+ years' experience in a combination of Quality Assurance and Clinical Operations roles within a regulated industry
- In depth knowledge of FDA, ISO, EMA, GMP, GCP and ICH quality systems and regulatory requirements for clinical programs including cell-based, gene-based, and rAAV-based therapies.

**OTHER QUALIFICATIONS:**

- Excellent interpersonal and collaboration skills
- Outstanding organizational skills
- Excellent written and oral communication skills
- Ability to operate in a fast-paced, multi-disciplinary industrial environment.

**An equal opportunity employer**

The above reflects management's definition of essential functions for this position but does not restrict the tasks that may be assigned. The above duties are representative only; management may assign or reassign duties and responsibilities to this position at any time.