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**Employment Opportunity/Job Description**

**Posting Title:** Quality Engineer

**Division:** iVexSol Quality Assurance

**Work Location:** Lexington, MA

**Job Type:** Full Time

**Employment Type:** Regular

**Job Description:** iVexSol, Inc. is a burgeoning vector manufacturing company founded on a truly transformative, next-generation technology that enables the creation of stable lentiviral vector producer cell lines for virtually any therapeutic gene. This technology will revolutionize the way gene therapy vectors are manufactured, sold, and employed by therapy providers, and in doing so, enable us to make a significant contribution to the elimination of suffering due to human disease. We are actively recruiting for creative and ethical teammates with the vision and courage to innovate **beyond** today’s perception of what is possible to transform vector production so that no patient is left waiting for a cure.

iVexSol’s Quality team is seeking a Quality Engineer who can operate with a high degree of independence to provide QA support for QMS development, maintenance, and communication along with performance of multiple Quality tasks, including but not limited to, maintaining and co-authoring documentation in support of various Quality Systems. Functions include Auditing, reports, developing, approving, and tracking corrective and preventative (CAPA) actions. Support of site external inspection readiness. The Department also provides quality/GMP guidance to site cross-functional personnel (i.e. QA, QC, Manufacturing, Facilities, Engineering, MSAT, R&D, etc.) ensuring resolutions are achieved for quality compliance escalations and potential risks.

**Responsibilities:**

* Draft and implement Quality System programs in a phase-appropriate manner for viral vector manufacturing.
* Draft, review, and manage approval of Quality System documentation.
* Support administration of Document Control and Training functions.
* Provide Quality support of change controls, investigations, CAPAs and effectiveness checks.
* Support inspection readiness activities and provide support during site inspections.
* Support vendor management program.
* Review documents and records through the Electronic Document Management System.
* Review executed batch records, and other executed quality records.
* Perform trending and analysis and provide metrics for Management Review.
* Support Internal Audits, as applicable.
* Stay abreast of changes in applicable regulations, directives and guidelines and determine its impact on company programs.
* Provide mentorship, guidance, and training to Quality and other GxP compliant personnel.
* Support and maintain a work environment in accordance with iVexSol’s core values (Learn, Create, Safety, Patients First, Integrity, Courage, and Team Work) while fostering open communication, collaboration, integration, and teamwork.
* Complete other duties and tasks as required.

**Minimal Job**

**Requirements:**

* Candidate must be authorized to work in the United States
* Candidate must have a BA/BS degree in a business or sciences related field, or equivalent experience. Preferred 2-5 years of combined Quality organization experience in a Life Science field. Experience in Cell and Gene Therapy is a plus.
* Must have proficient knowledge of regulations within Cell & Gene Therapy and phase-appropriate requirements leading up to cGMP production.
* Must have experience with GLP, GMP, ICH standards and regulatory guidance documents.
* Experience in a start-up or consulting is a plus.
* Must be an expert with MS-Word formatting, and proficient with other MS-Office tools (Excel, PowerPoint, etc.). Mac experience is a plus.
* Experienced with electronic document management systems or quality management systems.
* Must be extremely organized and detail-oriented, and able to handle multiple priorities in a fast-paced environment.
* Excellent written/oral communication skills.
* Strong problem solving and issue resolution skills.
* Be creative, innovative, communicative, collaborative, courageous, courteous, caring, careful, and consistently ready to do your best work
* Be able to work both independently and as a team member/leader
* During this time of a global pandemic, it is especially important that prospective applicants be familiar with SARS-CoV2 regulation and mitigation strategies. There will be on-site work for which you will be required to wear appropriate PPE when working in the same physical location with other team members, and be comfortable with rapidly changing rules and expectations with regard to this challenge.

**EEO Statement:** iVexSol Inc., is an Equal Opportunity Employer who endeavors to create and maintain a diverse environment. We do not discriminate in recruiting, hiring, training, promotion or any other employment practice for reasons of race, color, religion, gender, national origin, age, sexual orientation, marital or veteran status, disability, or any other legally protected status.

**Job Band:** 4

**Recruiter:** Heather Puksta, Head of QA

**Hiring Manager:** Heather Puksta, Head of QA

**Closing Date:** 12/1/2022

Please send CV and cover letter to: [Careers@ivexsol.com](mailto:Careers@ivexsol.com)