

**Employment Opportunity/Job Description**

**Posting Title:** Quality Manager

**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 Manager who can manage people, systems, processes and communicating across multiple levels within a company. The position will serve as a key point of contact for iVexSol’s QMS while performing multiple tasks, including but not limited to, maintaining and co-authoring compliant GMP and non-GMP documentation in support of various Quality Systems including the purchasing controls, lot release controls, audit management, supplier management, nonconformances, root cause analysis, and investigations. The Quality Manager is a Subject Matter Expert (SME) in multiple areas of Quality, a trainer for such processes, and will supervise and guide junior members of the organization.

**Responsibilities:**

* Provide flexible and novel approaches to Quality processes to start-up the company’s internal programs.
* Design, implement and manage various QMS elements including (but not limited to):
	+ A purchasing controls program by (but not limited to) developing and implementing SOPs for purchasing controls, materials management, supplier management, and quality technical agreements. In that, establish an approved supplier list, approved sourced materials list, and QTA template.
	+ An internal and external audit program. Establish an annual schedule for internal and external audits. Ensure audit schedule is executed as planned and conduct audits as appropriate. Follow-up on audit observations until adequate closure.
	+ Deviations, CAPAs, Change Control, and the maintenance of the lot genealogy system.
	+ Label Controls
	+ Recalls, Complaints Management, and
	+ Schedule, manage and perform audits.
* Review and approve records through the Electronic Document Management System.
* Review of master batch records, executed batch records, and other quality records.
* Perform trending and analysis as required and provide metrics to quality management as requested in preparation for Management Review.
* 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.
* 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.
* Complete other duties and tasks as required.
* This role will follow a hybrid model (virtual/on-site) until new facility is operational.

**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 5-8 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 GMP, GCP, ICH standards and regulatory guidance documents.
* Experience in a start-up or consulting experience 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.
* Confident supporting internal and external audits.
* 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:** 8/1/2022

Please send CV and cover letter to: Careers@ivexsol.com