

**Employment Opportunity/Job Description**

**Posting Title:** Document Control 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 Document Control Manager who can manage controlled document lifecycles and support all documentation needs across all levels and functional areas within the company. The position will serve as administrator of 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 System elements including the Learning Management System, Change Control, CAPA, Deviations, Investigations, Risk Management & Complaint Handling. The Document Control Manager performs the functions and duties of an archivist. This role will be the Subject Matter Expert (SME) in support of iVexSol’s electronic QMS (eQMS) roll out.

**Responsibilities:**

* Adhere to iVexSol’s QMS Policies and procedures to ensure continued compliance when maintaining and/or co-authoring GxP documentation in support of various Quality System elements.
* Facilitate the change control process and tracks it through development, approval, and implementation.
* Administer the training program, ensuring proper completion and filing of training materials for all employees.
* Analyze and interpret the significance of proposed changes using independent judgment and iVexSol procedures to guide change initiators in the development of accurate change requests.
* Review standard operating procedures, logs, forms, manufacturing records, work instructions and all other Quality documents and records for adherence to established templates, Good Documentation Practices and adequacy of referenced procedures and part numbers.
* Aid in the release of all controlled documentation by (but not limited to) providing information, solving problems, identifying issues, and entering information into various computerized systems.
* Function as QMS Administrator by (but not limited to) managing data migration, supporting end-users, and additional tasks associated with transitioning into a new eQMS system.
* Serve internal and external customers to meet the business needs.
* Act as administrator and gatekeeper for documentation during internal and external audits.
* Perform duties of archivist in compliance with pertinent regulatory requirements.
* 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 5+ years combined experience in Document Control, Quality, QMS, or similar GMP work experience, and 2+ years of experience in Pharmaceuticals or Biotechnology. Experience in Cell and Gene Therapy 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