

# Employment Opportunity/Job Description

Posting Title: Metrology and Maintenance Manager Division: iVexSol Global Technical Operations

Work Location: Lexington, MA

Job Type: Full Time; flexible schedule within core operating hours between 7am – 6pm

**Employment Type:** Regular

## Job Description

iVexSol, Inc. is a rapidly growing 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 patient suffering due to diseases. We are actively recruiting 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 is seeking an experienced Metrology and Maintenance Manager providing site coordination for routine calibration and maintenance activities in a cGMP environment supporting both laboratory operations and clinical manufacturing. The incumbent will manage these site programs for utility systems, facility & process equipment, manufacturing cleanrooms and lab infrastructure at our facility in Lexington, MA. This role will contribute to establishment of the programs, systems, and administration of service contracts and personnel to maintain compliant and inspection ready operations.

The individual will work in a cross-functional environment supporting site operations delivering on-time service, document administration, troubleshooting, and resolution of issues to align with internal customers.

## Responsibilities:

- Experience calibrating equipment in regulated environments such as: scales/balances, thermometers, temperature & humidity transmitters, pressure/vacuum, time, refrigerators/freezers, differential pressure, etc.
- Experience managing contract service providers and maintaining facility systems and equipment.
- Supervise visiting calibration, preventative maintenance, and validation vendors
  Assisting with the processing, tracking, reviewing, and trending of GxP
  maintenance and calibration work orders through the computerized maintenance
  management system (CMMS)
- Cross functionally coordinates schedules of all Maintenance and Calibration activities
- Experience with calibration & maintenance databases \*BMRAM preferred\*.
- Manages 3<sup>rd</sup> party calibration documents



- Assist with calibration/maintenance data review, entry, and archiving for cGMP records.
- Support the development, review, and approval of calibration and maintenance plans in site CMMS or BMRAM system.
- Prepare, revise, and review calibration and /or maintenance Standard Operating Procedures (SOP).
- Support internal customers through review, prioritization, and response to equipment maintenance/repair requests by establishing service levels and communicating status updates.
- Participate in routine maintenance, out of tolerance reconciliation, and change control, deviation, and investigation activities.
- Independently maintains assigned training curriculum for Operations, Facilities and EHS.
- Provide input to staffing plans, assist in interviewing process, to orientate, mentor and train group staff or other resources as needed.
- Interact with Accounts Payable and Supply Chain to maintain inventory, including quantity and invoicing issues.
- Track spare parts and inventory needs for equipment and site systems critical spares
- Support additional facility related task as assigned.

### Minimum Requirements

- Associates or Bachelor's Degree in Engineering or equivalent technical discipline preferred
- 4+ years' experience within a cGMP environment.
- Work experience in Life Sciences / Pharmaceutical / Medical Devices industries is required.
- Working knowledge of cGMP requirements / principals including ISPE and FDA guidelines.
- Proven ability to work independently managing multiple tasks effectively in a fastmoving, dynamic small company environment.

#### **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.

Hiring Manager Sean Brown, SVP Operations

Closing Date: 04/30/2023

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