

Employment Opportunity/Job Description

Posting Title: Facility Engineer

Division: iVexSol Global Operations

Work Location: 20 Maguire Road, Lexington, MA

Job Type: Full Time Employment Type: Regular

iVexSol is seeking a Facilities Engineer to serve as the Lexington MA SME in maintaining its site facility infrastructure, site utility systems, lab and production equipment. The role will provide SME leadership, guidance, and support within iVexSol while working to maintain the facilities site system and infrastructure. The incumbent will report to the Director of Facilities

Essential Functions:

- Act as Facilities SME for its systems and support programs. May extend to satellite facilities when required.
- Authoring and maintaining facility infrastructure and site system procedures.
- Participate in the performing, planning and management of:
 - maintenance of leased space infrastructure, HVAC and site utility systems
 - day-to-day facilities support to meet manufacturing activities
 - GMP facility environmental alarms response
 - capital projects within budgets and timelines
- Reviewing applicable site systems engineering documentation: equipment lists, instrument lists, drawings, specifications, and submittals to ensure quality, accuracy, and applicability.
- Maintain/Optimize build-out and maintenance of spares parts program, maintenance strategies, and ensure they are fully documented on the site Maintenance system (CMMS).
- Ensuring that facility operates in compliant manner, initiating deviations when events occur and implementing any resulting CAPAs.
- Performing field walk downs to ensure new installations meet design requirements.
- Identifying deficiencies during installation and commissioning and ensure correction in a timely manner.
- Assist in identifying maintenance & calibration requirements for existing and new equipment.
- Assist the Commissioning and Qualification teams.
- Perform technical troubleshooting of site systems and facility equipment.
- Support Regulatory activities, including vendor and agency preparations and inspections.



Required Skills and Qualifications:

- Bachelor's degree in chemical, biological, mechanical, electrical engineering or related discipline or equivalent work experience required 6-8 years (Sr Engineer) or 8-10 years (Manager) experience in the biotech engineering/manufacturing environment.
- Direct experience supporting manufacturing facilities and utility systems within an FDA/EMEA regulated environment.
- Knowledge of safety, GMP, and environmental regulatory requirements.
- Fundamental knowledge of GMP equipment, utility, and cleanroom design/installations.
- Strong understanding of industry standards for commissioning, validation, and operation of facilities and utilities for cGMP manufacturing and GMP laboratories.
- Experience with Metrology & Preventive Maintenance Programs and Automation Engineering a plus.
- Experience with a GMP facility startup and single-use technologies.
- Dedicated team player who is able to withstand the high demands of a fast-paced environment.
- Excellent written, organizational, and verbal communication skills are essential.
- Strong planning and organizational skills.
- Comfortable working independently with minimal supervision.
- Highly organized, results driven, problem solver and collaborator.

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:

Salary/Equity: Competitive salary, Equity, Healthcare, 401k included, other benefits

available.

Closing Date: TBD

Please send CV and cover letter to: <u>Careers@ivexsol.com</u>