On Demand Pharmaceuticals, Inc.: Director of GMP Engineering

On Demand Pharmaceuticals (ODP) (www.ondemandpharma.com) is changing the way we make and distribute medicines—by providing them to anyone, anywhere, anytime. ODP is creating innovative manufacturing platforms to enable our vision to produce critical medicines at the point of care and to secure the pharmaceuticals supply chain. As a young organization, ODP offers an exciting opportunity for passionate scientists and engineers to make a difference in the world while developing career paths for advancement. ODP is seeking a Director of GMP Engineering to support GMP Manufacturing operations.

Summary:

This position is the leader of ODP's activities in GMP Plant / Process Engineering, Maintenance, Metrology, Commissioning, Qualification and Validation (CQV) program for equipment, and utilities / HVAC for API synthesis, tableting, and aseptic manufacturing. The candidate is responsible for the development, implementation and continuous improvement of safe, compliant, and effective facilities and engineering activity in support of our manufacturing operations and other facilities. The scope of the role covers site equipment and facilities maintenance and calibration programs, facility master planning, new projects capital planning, execution and budget. The candidate is responsible for building a team and managing contractors that will deliver the reliable and uninterrupted operation of the manufacturing site, critical equipment, and facility projects, and maintain a continuous improvement program that will have a direct impact on growth and success.

This candidate also will be a key contributor to ODP's facility design and construction effort, as well as the design and development of ODP's systems.

Responsibilities:

- Develop and implement organization design to support functional areas including Maintenance, Systems Engineering, Calibration, Automation, Equipment and Computer Systems Validation, Site Services, and EHS
- Working with the Director of GMP Operations, develop reliability-centered maintenance process for preventing, predicting, and measuring scheduled and unscheduled equipment down time
- Ensure compliance with safety practices and government regulations as they pertain to the normal operating activities of the facility, including FDA requirements, GMP best practices, including Data Integrity, and Quality Assurance policies and procedures
- Establish and/or mature current maintenance program including but not limited to, instrumentation, calibration, preventative maintenance, setting up spare parts and mitigating business continuity risks and ensuring equipment uptime
- Work with the facilities department to maintain GMP utilities operations and management of building systems
- Interface with safety, operations, and quality personnel to ensure facility operations and systems comply with required standards
- Develop solutions to complex issues and Facilities / Engineering initiatives with cross-functional team leaders, following cGMP regulations and internal procedures in accordance with applicable regulatory standards
- Lead / oversee equipment- and system-related investigations, CAPAs, deviations and change controls, review and approve records (change controls, test records, validations, protocols, etc.)

- Support regulatory, partner and internal audits
- Oversee CQV activities and associated program
- Lead effort for equipment decommissioning and system retirement
- Review and approve Engineering-related Standard Operating Procedures
- Contribute to User Requirements Specification, Functional Requirements Specification, and Detailed Design Specification development
- Contribute to System Level Impact Assessments, and Component Classification activities
- Develop and execute Qualification documents such as IQ, OQ, PQ, Traceability Matrices, and Summary Reports
- Scope, specify, and lead new equipment projects and equipment modification projects
- Lead effort for new project and system cost estimation, Return on Investment, and payback period
- Lead the team which serves as System Owner and Subject Matter Expert for GMP equipment and systems
- Contribute to definition of GMP data collection needs, including storage interval and reporting
- Contribute to alarm limit definition, including guard-banding for critical process parameters
- Participate in Process Safety Reviews
- Identification and Management of Critical Spare Parts
- Assist in the development of equipment operational SOPs and associated training
- Support the Automation functional group in defining HMI needs, alarm management, and process control strategies
- Perform other administrative/managerial duties as required

Minimum Hiring Standards:

- Bachelor's degree in an engineering field required.
- Master's degree preferred.
- Minimum 5 years of Facilities and/or Engineering experience in the biotechnology or pharmaceutical industries required.
- Minimum 5 years of experience leading a Facilities & Engineering group.

Please click here to submit an application for this position.

On Demand Pharmaceuticals is an equal opportunity employer. On Demand Pharmaceuticals does not discriminate in employment with regard to race, color, religion, national origin, citizenship status, ancestry, age, sex (including pregnancy, gender identity, or related medical conditions), sexual orientation, marital status, physical or mental disability, past or present military service or any other characteristic protected by law