On Demand Pharmaceuticals, Inc.: Associate Director of GMP Manufacturing Operations

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 an Associate Director of GMP Manufacturing to support GMP Manufacturing operations.

Summary:

The Assistant Director, GMP Manufacturing Operations will assist in the build out of the manufacturing area and will support product manufacturing, aiding in achieving departmental milestones, and supporting the management of the Manufacturing team.

Responsibilities:

- Work directly with internal and external stakeholders to execute renovation and establishment of our GMP suite and capabilities.
- Supports the execution of ODP manufacturing operations, including hiring, development and training of personnel
- Contribute to identification and development of future business models
- Supports management, development and training of Manufacturing Team to execute on established targets.
- Provides input to and works directly with our scientists and engineers to a) inform development of our platforms and future innovation efforts, and to b) ensure optimal tech transfer of our technology from development to the manufacturing arena.
- Assist in oversight of manufacturing operations at the facility to manufacture precursors, API, and/or drug product according to approved protocols, regulations, and schedules.
- Manages key manufacturing metrics/site goals, supports critical program milestones, and executes continuous improvement initiatives.
- Rapidly and accurately escalates issues to Management and corrective action to resolve manufacturing and facility issues and mitigate any supply disruptions.
- Supports validation activities involving Drug Product Manufacturing equipment and processes
- Works effectively with other departments, such as Quality Assurance, Facilities, Engineering, Project Management, Business Development, Regulatory, Quality Control, IT, and Supply Chain.
- Execution of schedules, production plans, and material requirements.
- Supports the effective use of material, equipment, and personnel in producing quality products.
- Supports budgets for the facility and manufacturing operations.
- Participates in cGMP audits of production areas within the facility and helps address deficiencies as required
- Maintains area inspection readiness for regulatory and client audits
- Writes and reviews SOPs, specifications, regulatory filing, or other controlled documents as needed
- Provides technical input to resolve manufacturing process challenges
- Maintains awareness of recent developments in industry

- Ensures that safety standards are maintained.
- Embodies Company's cultural values and aligns daily actions with goals and company culture

Minimum Hiring Standards:

- Bachelor's degree in the physical or biological sciences, or chemical engineering required.
- Minimum of 5 years cGMP experience, aseptic / sterile processing preferred
- Minimum 1 – 2 years Leadership/Management experience
- FDA inspection experience preferred
- Understanding of aseptic processes, equipment, automation, validation, cleanrooms, and other classified area requirements
- Knowledge of device assembly and finish labelling & packaging operations
- Working knowledge of industry practices, regulations and experience interacting with multiple health authorities
- Skilled at Interdepartmental Relationships (Quality Assurance, Facilities, Supply Chain, Project Management, etc.) and efficient at removing barriers
- Proven ability to drive accuracy and results
- Working knowledge of high paced manufacturing environment
- Strong management and interpersonal skills.
- Ability to work collaboratively with multi-disciplinary cross-functional teams
- Strong written/oral skills required, and ability to communicate technical concepts to a non-technical audience
- Energy and passion to thrive in a start-up environment and to deliver on the mission of On Demand Pharmaceuticals.

Preferred Hiring Standards:

- Master's degree or higher preferred
- Experience with Lean/Six Sigma quality systems helpful
- Individuals with > 5 years' experience and training preferred.
- Experience in continuous processing of chemicals, materials, or pharmaceuticals

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.