Manufacturing Manager

Location: Rockville, MD [100% on-site]

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 Manufacturing Manager to support GMP Manufacturing operations.

Summary:

The Manufacturing Manager 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:

- Oversee manufacturing of precursors, API and/or drug product according to approved protocols and regulations.
- Execution of manufacturing schedules, production plans, and material requirements in achieving departmental deliverables.
- Provides input on renovations and improvements of the GMP Manufacturing areas.
- Contribute to identification and development of continual process improvement initiatives.
- Oversee the management, development and training of Manufacturing Team .
- Provides input and works directly with scientists and engineers to a) informed development of our platforms and to b) ensure optimal tech transfer o from development to the manufacturing arena.
- Collects key team metrics/site goals in support of critical program milestones.
- Rapidly escalates issues and provides suggested corrective actions to resolve manufacturing to mitigate any supply disruptions.
- Supports validation activities involving Drug Product Manufacturing equipment and processes
- Works effectively with other departments including Quality Assurance, Facilities, Engineering, Project Management Quality Control.
- Writes and reviews SOPs, specifications, regulatory filing, or other controlled documents as needed.
- Supports the effective use of material, equipment, and personnel in producing quality products.
- Participates in internal cGMP audits of quality systems and helps address deficiencies as required.
- Maintains area inspection readiness for regulatory and client audits.
- Provides technical input to resolve manufacturing process issues.
- Maintains awareness of recent developments in industry.
- Ensures that safety standards are maintained.
- Supports company's values and aligns actions company culture

Minimum Hiring Standards:

- Bachelor's degree in the physical or biological sciences, or chemical engineering required.
- Minimum of 3 years cGMP experience with aseptic / sterile processing
- Minimum 1 – 2 years Leadership/Management experience
- Proven understanding of aseptic processes and equipment

- Working knowledge of industry practices and regulations
- 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 communication skills
- 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
- Experience with Lean/Six Sigma quality systems helpful
- Individuals with > 5 years' experience and training
- Experience in continuous processing of chemicals, materials, or pharmaceuticals
- Regulatory inspection experience

Please click here to submit an application for this position.

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