On Demand Pharmaceuticals, Inc.: Quality Control (QC) Lab Manager

On Demand Pharmaceuticals (ODP) (www.ondemandpharma.com) is changing the way we make and distribute medicines—by providing them to everyone, everywhere, every time. 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 **Quality Control (QC) Lab Manger** to support the establishment and operation of our QC cGMP laboratory. Our QC lab will perform analytical testing of pharmaceutical staring materials, in-process samples, and release testing of pharmaceutical drug substance and drug products. ODP has an established R&D analytical lab which is responsible for developing and/or assessing compendial and non-compendial methods. These methods will be transferred to the QC lab for validation and/or verification as per ICH and USP guidelines.

Summary:

The QC Lab Manager will lead the establishment of our QC lab including but not limited to: equipment receipt and installation, lab operations and procedures, good documentation practices and data management, training of QC analysts. Project involvement will start with cGMP lab infrastructure and operation needs and will continue through method development, verification and/or validations, on to routine analysis of cGMP starting materials, in-process samples, and release testing of cGMP pharmaceutical products. A combination of analytical, communication and reasoning skills to accurately and efficiently established the required infrastructure and run a QC lab is a must.

Responsibilities:

- Establishment of a cGMP QC laboratory for pharmaceutical products following regulatory standards.
- Creates systems/procedures for recording, monitoring, and maintaining quality results to ensure QC laboratory performance is kept in accordance with cGMP and company procedures.
- Responsible for the overall operational and technical efforts of QC lab including staff members and equipment maintenance, by directing the day-to-day operations in addition to execution of lab testing of GMP samples.
- Review and compile laboratory test data and perform appropriate analyses.
- Provides technical expertise for manufacturing deviations e.g. OOS investigations, by working in concert with manufacturing and quality assurance. This includes deviation documentation, investigational reports, change control, CAPAs etc.
- Writing, reviewing and approving documentation e.g. technical reports, standard operating procedures, laboratory protocols, trend analyses.
- Quickly identify and resolve gaps and provide technical support while troubleshooting problems such as equipment, software, data.
- Facilitate the maintenance of the lab including routine housekeeping, lab inventory, and equipment
- Contribute to team building, training, and problem-solving initiatives
- Professionally develop analysts to improve on individual and overall performance
- Communicate effectively with other relevant groups, including but not limited to Quality Assurance, Manufacturing, and Process Development
- Contributes to completing project milestones, organizing work to meet project deadlines, and communicating progress on scheduled projects.

Minimum Hiring Standards:

- Bachelor's degree in relevant scientific discipline; an advanced degree is preferred
- Minimum of 5 years of work experience in Quality Control of pharmaceutical products
- Experience in managing a cGMP laboratory
- Knowledge of following analytical methods/equipment: GC, LC, ICP-MS, KF, LOD, ROI, optical rotation, RI, stability analysis, light obscuration, potentiometric titrations, spectroscopy.
- Knowledge of FDA regulations regarding the manufacturing of small molecule pharmaceuticals
- Applied knowledge of GXP and USP guidelines
- Ability to comprehend regulatory requirements and technical documentation and objectively make decisions
- Track record of being a motivated self-starter
- Exemplary verbal, written, communication, multi-tasking, and organizational skills
- Experience with qualification, technology and method transfer, and validation/verification of analytical methods
- Energy and passion to thrive in a start-up environment and to deliver on the mission of On Demand 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.