On Demand Pharmaceuticals, Inc.: Director, Quality Systems

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 leaders to make a difference in the world while developing career paths for advancement. ODP is seeking a Director, Quality Assurance to support the development of our next generation medicine manufacturing platforms. Our manufacturing platform is comprised of modules that can chemically synthesize active pharmaceutical ingredients, purify crude products, and formulate into finished drug product. These modules are miniaturized and mobile and can be deployed anywhere in the world to strengthen the pharmaceutical supply chain and enable local production of medicines. Working with the Chief Medical Officer & VP for Quality & Regulatory Affairs, this leader will be responsible for helping design and implementing ODPs Quality Management System. This role will be responsible for ensuring that all quality requirements of the Company are met in a timely fashion during a period of rapid growth. Thus, the successful candidate will possess an expert knowledge base and extensive experience in the current regulatory and quality space, as well as a demonstrated ability to be forward thinking, creative and innovative.

Responsibilities:

- Design and implement ODP's Quality Management System
- Perform and coordinate the QA/QC department and duties within. Responsible for overseeing and ensuring, quality policy and regulatory obligations, are implemented and followed company-wide.
- Review SOPs, STPs and revise accordingly
- Maintain all Quality Assurance and Quality Control master files
- Review and update Quality manual accordingly
- Prepare and carry out validation activities as required.
- Perform internal and vendor audits.
- Documenting and reviewing quality requirements and agreements of raw materials with suppliers
- Investigating and providing suggestions for quality and health and safety
- Ensuring that manufacturing processes comply with standards
- Work with operating staff to establish procedures, standards, systems
- Documenting and determining training needs
- Recording, analyzing, distributing and archiving statistical information
- Provide senior quality expertise and leadership for the company, customers and external third parties.
- Manage quality personnel and assets, to ensure all quality activities are achieved according to agreed schedules, budgets and organizational objectives.
- Direct Quality Operations in driving compliance activities related to FDA regulations, and quality systems standards.
- Oversee development and implementation of training programs for direct reports and other functional groups to assure awareness of all requirements and maintain compliance with all current regulation.

Hiring Standards:

- Bachelor's degree; Degree in Chemistry, Biology or related life science is preferred. An advanced degree in Life Sciences, such as a Ph.D. is desirable.
- Minimum of ten (10) years of experience working in a GMP environment.
- Minimum of ten (10) years of experience in a Quality role in a pharmaceutical manufacturing environment.
- Expert knowledge of quality systems and culture, GMP regulations and legal product registration processes for API and Pharmaceutical products

- Strong and demonstrated leadership skills, problem solving ability along with associated analytical and communication skills
- Proven experience in leading and managing QA functions through teamwork, collaboration, and open communication
- Successful track record of working in a fast-paced environment while building strong partnerships with others internal and external to the organization
- Energy and passion to thrive in a start-up environment and to deliver on the mission of On Demand Pharmaceuticals

Preferred Experience:

- Experienced in 21 CFR Part 211 Quality Management Systems (5 years)
- Experienced in ISO 13485 Quality Management Systems (5 years)
- Experienced in SOPs, Reports and Document Control (5-10 years)
- Experienced in Complaint Handling, CAPA, NCMR (5-10 years)

Application materials:
Send a letter of intent and resume/CV to:
John J. Lewin III, PharmD, MBA
Chief Medical Officer
john@ondemandpharma.com