On Demand Pharmaceuticals, Inc. Manager, Quality Management System

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.

This position supports and enables 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 products. These modules are miniaturized and mobile and can be deployed anywhere in the world to strengthen pharmaceutical supply chain and enable local production of medicines. Reporting to the VP for Quality & Regulatory Affairs, this position will have growth opportunity and responsibilities such as:

Growth Highlight:

- Room for growth in this role for a director level Quality professional
- Unique combination of experiences in the most cutting edge end-to-end continuous cGMP pharmaceutical manufacturing and medical device development and manufacturing.

Responsibilities:

- Lead quality management system (QMS) development, implementation, and execution to US and international regulations and standards, including compliance to cGMP, ISO13485:2016, US 21 CFR requirements.
- Maintain a compliant and effective Document Control and Change Control process, with a cGMP manufacturing facility in scope.
- Manage the Internal and External QMS Audit programs; ensuring audit compliance and adequate follow-up to audit nonconformances.
- Develop and ensure the effectiveness of the deviation and CAPA program, with support from QA Scientists and QA Engineers.
- Support Management Reviews, serving as Quality System Management Representative (QSMR) with responsibility for generating required performance metrics and reporting the effectiveness of the QMS, to top management and identify any need for improvements to maintain compliance with regulations.
- Manage test methods and inspection procedures and the implementation of process control systems to support the development, qualification, and on-going pharmaceutical and/or medical device manufacturing activity, with a heavy emphasis on computerized systems.
- Manage a risk-based supplier qualification program, including qualification of suppliers, supplier corrective actions, supplier audits and review of Quality Agreements.
- Support risk management programs and partner with chemistry, engineering and manufacturing process development to drive design control processes.
- Partner with QA Scientists and QA Engineers, to support the development of validation strategies in partnership with Manufacturing Engineering to support production transfer of design projects.
- Partner with cGMP manufacturing team, review and/or approve documents including: Manufacturing batch records in support of product release; SOPs, Validation Protocols and Reports.
- Partner with QC personnel, support the maintenance and reporting of routine product bioburden and endotoxin monitoring for all applicable products
- Support Operations Team in the maintenance of a robust Environmental Monitoring program for the company's controlled-environment areas.
- Proactively investigate and analyze customer complaints, and oversee problem reporting to regulatory agencies.

- Coach and develop team members and supervise/train quality associates.
- Other QMS related responsibilities.

Minimum Requirements:

- Bachelor's degree in basic or applied science; an advanced degree is preferred
- Minimum 5 years of working experience in pharmaceuticals, medical device or other regulated industries and 3 years working experience focusing on QMS
- Experienced in using all electronic QMS tools.
- Working experience with ISO 13485:2016, ISO 14971, 21 CFR Part 210, 21 CFR 211
- Familiarity with ICH guidelines
- Working experience with electronic QMS, and qualification of computerized systems
- Ability to work with cross-functional teams and build strong working relationships

Desired Competencies:

- Strong analytical, critical thinking and communication skills and team orientation
- Start-up or small company experience
- Experience in new product/process development and method/production transfer
- Experienced in establishing cGMP operations
- Excellent attention to detail, time management and investigative skills, as well as the ability to manage multiple priorities with aggressive timelines
- Innovative mindset and problem-solving approach
- 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 sexual harassment), sexual orientation, marital status, physical or mental disability, military status or unfavorable discharge from military service or any other characteristic protected by law.