On Demand Pharmaceuticals, Inc. Sr. QA Manager

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 Sr. QA Manager supports the operations of our next generation medicine manufacturing platforms. Our manufacturing platform is comprised of modules which 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 Director of QMS, this position will be responsible for:

Responsibilities:

- Provides compliance leadership and support on the execution of manufacturing activities per cGMP, SOPs and project specifications, of various pharmaceutical products.
- Help the team in GMP manufacturing processes, analytical methods, batch disposition and etc.
- Draft, review, or approve Standard Operating Procedures related to QA functions, Change Controls, Deviation Investigations, and Final Reports at conclusion of protocol / study execution to ensure compliance with GMP regulations, guidance, and corporate policies.
- Develop, utilize, and lead handling of issues, nonconformances, deviation, CAPA, and change systems for CMC/manufacturing activities.
- Responsible for raw materials, components (including packaging and labeling), in-process inspection, and final product oversight.
- On-the-floor support during manufacturing, including for sterile products.
- Lead daily process quality audits of manufacturing lines. Analyzing quality trends. Investigate and identify underlying issues, including raw materials, process parameters, operator actions, etc.
- Review and approve batch records, including resolving deviations, CAPAs and etc.
- Review qualification, calibration, and maintenance records for and approve release of GMP equipment.
- Review building, environmental and process alarms, and investigate excursions with SMEs and stakeholders.
- Management of the risk assessment process related to manufacturing.
- Review and/or approve other documents related to but not limited to manufacturing. For example, IQ/OQ/PQ protocols and reports, test methods, or validation protocols, reports and related deviations.
- Provide related procedures, documents, and records oversight.
- Lead the development, implementation and maintenance of Quality procedures, and systems to ensure the quality of bulk manufactured products and services in accordance with quality specifications, company, customer, and GMP/Regulatory requirements.
- Provide Quality support in operations and facilities.
- Represent QA GMP/Manufacturing on project teams, management teams, and in other forums.
- Oversee and provide required QA training with a focus on GMP and manufacturing.
- Provide guidance on day-to-day issues in GMP Operations and facilities, and ensure processes and procedures are followed.
- Guides Operations in establishing Standard Operating Procedures for manufacturing and laboratory processes that coincide with cGMP requirements
- Evaluate QA activities for effectiveness and take responsibility for evaluation and driving the need to make the necessary improvements and ensure that the improvements are appropriately implemented.

Minimum Requirements:

- Bachelor's degree in basic or applied science. An advanced degree is preferred.
- Minimum 5 years of working experience in pharmaceuticals industry, preferably manufacturing site.
- Working experience with quality risk management.
- Knowledge in GMP manufacturing, QbD, DoE, analytical methods, batch disposition.
- Possess in-depth knowledge of FDA and GMP regulations, guidance, principles, concepts, and industry best practices.

Desired Competencies:

- Knowledge of applicable quality systems and accreditation, licensing and/or certification requirements.
- Experience managing people providing leadership / feedback / development for personnel.
- Ability to work with cross-functional teams and build strong working relationships.
- 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 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.