Director or Associate Director of Microbiological & Sterility Assurance Quality Specialist
Location: Rockville, MD
Type: Full-Time

On Demand Pharmaceuticals (ODP) is changing the way we make and distribute medicines—by providing them to everyone, everywhere, 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 Scientist to support the development of our next generation medicine manufacturing platforms and the commercialization of generic medicines. 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 pharmaceutical supply chain and enable local production of medicines.

Summary of Job Position: Oversee all microbiological & sterility control efforts at ODP (including all external microbiological testing efforts and establishment of internal testing capabilities). Subject matter expert liaison with the FDA as necessary.

Responsibilities:

- Design and author quality documentation, including but not limited to, SOPs, training procedures, policies, contamination control, OOT, OOS, CAPA, etc.
- Review and approve microbiological and sterility assurance quality documentation, including but not limited to test methods and validation reports, media fill protocols and executed protocols.
- Oversee all microbiological & sterility control efforts at ODP (internal & external)
- Establish internal capabilities, this may include the establishing of a Microbiological quality testing laboratory capability at headquarters.
- Review, approve, and/or trending of quality data including but not limited to, endotoxins, sterility, contamination control, cleaning, environmental monitoring, other microbiological and physiochemical test data.
- Communicate across disciplines and team, e.g. QA, GMP manufacturing, GMP engineering, tech transfer, research, and development.
- Support inventory management needs.
- Comply with all company policy and standards, including, but not limited to GDP, data integrity, etc.
- Assist with other analytical/quality services, as needed.
- Educate and train staff members.
- Interface with the FDA as a subject matter expert.
- Author CMC sections of regulatory fillings as needed.

Minimum Hiring Standards:

- Minimum of a master's degree in microbiology, or related field. PhD in microbiology is preferred.
- At least 7 years of experience in a GMP microbiological quality environment
- cGMP training including FDA and ICH guidelines
- Experience working with sterile injectable products
- Experience in environmental monitoring

- Experience with regulatory fillings
- Ability to write/type/review large volumes of information with excellent attention to detail
- Ability to understand analytical techniques related to cGMP manufacture of pharmaceutical products
- Experience in quality documentation generation, review and approval
- Experience in modern analytical testing & test methods including antimicrobial effectiveness testing, sterility testing, endotoxin testing
- Ability to work collaboratively with multi-disciplinary cross-functional research teams
- Energy and passion to thrive in a start-up environment and to deliver on the mission of On Demand Pharmaceuticals
- Experience in training, supervising and/or managing junior staff
- Demonstrated self-starter and adept in practicing self-accountability

Physical Demands/Work Environment:

- Ability to safely handle hazardous materials
- Ability to move 50 pounds
- Ability to bend to reach floor level
- Ability to wear respirator

Please click here to submit an application for this position.

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