On Demand Pharmaceuticals, Inc.: Senior Project Manager for Chemistry, Manufacturing and Controls

On Demand Pharmaceuticals (ODP) (www.ondemandpharma.com) seeks to change the way medicines are made and distributed to make them available to anyone, anywhere, anytime. ODP is creating innovative modular manufacturing platforms to enable our vision to produce critical medicines at the point of care and to secure the pharmaceuticals supply chain. ODP is seeking a Senior Project Manager for Chemistry, Manufacturing and Controls (PM CMC) to prepare and submit regulatory applications to include drug master files (DMF) for active pharmaceutical ingredients and abbreviated new drug applications (ANDA) for drug products.

The Senior PM for CMC will be responsible for working with a multi-disciplined team within a start-up organization to:

- Liaise with chemical, engineering, and operations teams to integrate CMC requirements into the ODP master schedule and identify risk mitigation strategies for CMC critical path activities that will ensure timely submission of DMF and ANDA applications to the Food and Drug Administration (FDA).

- Manage day-to-day CMC activities related to the preparation of DMF and ANDA applications, such as process development reports and manufacturing batch records, for 4-5 assets and identify resource allocation needs to meet submission deadlines.

- As needed, coordinate efforts with Contract Development and Manufacturing Organizations (CDMO) and Contract Research Organizations (CRO) to obtain specific input required for FDA applications.

- Integrate technical writing into cohesive and coherent FDA applications and deliverables and prepare executive summaries for briefing to ODP leadership.

Candidate Qualifications

- Experience in submitting multiple drug master file (DMF) and abbreviated new drug applications (ANDA) to the Food and Drug Administration.
- Over 7 years of experience in planning and managing cross-functional aspects of pharmaceutical product development including: API synthesis, formulation and drug product technologies.
- Working knowledge of current good manufacturing practices (cGMP), good laboratory practices (GLP) and good documentation practices (GDP).
- Demonstrated ability to implement CMC project management tools such as, CMC Database, OnePager Pro, MS Project, ePlan/Planisware, DOI Tool, Right First Time Scorecard, Operational Risk Management
- Highly organized and able to work on multiple tasks in a fast-paced environment.
- BS or MS in Chemistry, Biotechnology, Life Sciences or related scientific field

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.