On Demand Pharmaceuticals, Inc.: Associate Director of Regulatory Affairs

On Demand Pharmaceuticals (ODP) is changing the way we make and distribute medicines—by providing them to everyone, everywhere, every time. 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 an Associate Director of Regulatory Affairs to support our team.

Position Responsibilities:

- Ensuring timely development of regulatory strategies.
- Lead and support regulatory agency meetings including meeting preparation and briefing document creation; Ensure timely and sound responses to regulatory agency requests.
- Lead the creation and submission of US FDA filing and potentially international dossiers.
- Build, manage and lead the regulatory affairs team.
- Assess and strategize post-approval changes and relevant submission. Strategically interpret and communicate regulatory requirements to development teams.
- Proactively identify project issues, reports progress regarding objectives and plans and implement appropriate regulatory strategies to mitigate risks.
- Provide guidance and support CMC development lifecycle including chemical synthesis, process characterization and optimization, control strategy, and etc.
- Lead internal review and approval process for CMC related submissions and regulatory questions.
- Prepare regulatory impact assessments for change control management and deviation reports
- Provide guidance and perform technical review of analytical test methods, specifications, and stability protocol/report/data.
- Coordinate timely & accurate assembly of responses to inquiries from the FDA on CMC content.
- Lead the author CMC amendments, supplements, and annual reports.
- Support internal audits and external inspection and/or audit from regulatory agencies and/or notified bodies, focusing on CMC.
- Support and prepare other CMC ad-hoc requests at the pre & post-approval stage of the product
- Provide consultancy regarding drug development including timeline management.

Qualifications:

- MS or higher in Chemistry, Biology, Chemical Engineering, or related field.
- 7+ years' experience in authoring and/or review of CMC sections for DMF, NDA, BLA, IND, and/or IMPD, preferably of generic drugs.
- Strong knowledge, deep understanding and demonstrated practice of 21 CFR part 210, 211, 11 and cGMP.
- Ability to work with stakeholders from cross-functional team, including development team, GMP Operations and etc. internally and contract service suppliers.
- Detail-oriented team player with strong written and oral communication skills.

- Ability to manage several projects simultaneously, creative in developing strategies for solving problems, and is driven by project requirements such as milestones and timelines.
- Working experience with 503(b) is highly desirable.

COVID-19 Vaccination Policy: With limited exceptions, up to date COVID-19 vaccinations are required for all ODP employees who work on-site at our headquarters. Employees must present proof of up-to-date vaccination (ex. CDC card) or submit exemption requests to the Director of People Operations before their start date. Exceptions to the policy are available only for those who need an accommodation for a qualifying medical reason or sincerely held religious belief or practice.

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.