On Demand Pharmaceuticals, Inc.: 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 Director of Regulatory Affairs to support our team.

Position Responsibilities:

- This position functions with a high degree of independence and provides global regulatory oversite for sterile products.
- The Director shall bring energy, and innovation and oversee the Regulatory Department and direct reports.
- Provide leadership guidance by directing the Global Regulatory Team which coordinates cross functional regulatory support for development of marketed products
- Develop and lead the worldwide regulatory strategy to optimize sterile processes and obtain shortest time to approval by regulatory agencies overseeing multiple indications simultaneously.
- Leader role and project management for the regulatory division.
- Global leader for IND, BLA and NDA managing the regulatory team, and submission operations, key contact with Global Regulatory Bodies.
- Strong expertise in leading the regulatory requirements of 503a and 503B sterile compounding.
- Leader for ODP preparation, review and submission of CMC content for submissions of all types and their amendments and supplements for US FDA, Health Canada, Japan and EU.
- Global Leader for policy and advisor and oversees the teams on impact of regulations, laws and global guidance.
- Lead and oversee development of regulatory strategies ensuring team meets timely milestones.
- Oversee and Lead global regulatory agency meetings ensuring meeting preparation; Ensure timely and sound responses to regulatory agency requests by the team of regulatory professionals.
- Oversee and responsible for leading the creation and submission of US FDA filing and international dossiers.
- Oversee post-approval changes and relevant submission. Strategically interpret and communicate regulatory requirements to development teams and regulatory professionals.
- As lead proactively identify project issues, reports progress regarding objectives and plans and implement appropriate regulatory strategies to mitigate risks and remove roadblocks.
- Global leader for CMC development lifecycle including, sterile processing, chemical synthesis, process characterization and optimization, control strategy, and etc.
- Global Leader internal review and approval process for CMC related submissions and regulatory questions.
- Oversee regulatory impact assessments for change control management and deviation reports and microbial investigations and assessments for environmental controls.
- Lead and provide guidance and perform technical review of microbial methods, endotoxin studies, analytical test methods, specifications, and stability protocol/report/data.
- Coordinate timely & accurate assembly of responses to inquiries from the FDA on CMC content and sterility assurance.

- Oversee and lead the author CMC amendments, supplements, and annual reports.
- Drive and support internal audits and external inspection and/or audit from regulatory agencies and/or notified bodies, focusing on CMC.
- Oversee and support and prepare other CMC ad-hoc requests at the pre & post-approval stage of the product
- Oversee and provide consultancy regarding sterility requirements, microbiological requirements, drug development including timeline management.

Qualifications:

- **This is an ODP office based role located in MD.**
- **Experience in leading a team of Regulatory Experts**
- Ph.D in Microbiology required.
- 15+ years' experience in authoring and/or review of CMC sections for DMF,ANDA, NDA, BLA, IND, and/or IMPD, preferably of sterile, small and large molecule .
- Expert knowledge, deep understanding and demonstrated practice of 21 CFR part 210, 211, 11, 600, 800, 314 cGMP.
- Extensive 503A and 503B Pharmacy Compounding Knowledge and expertise required and direct experience in leading FDA 503B Inspections with proven track record of success.
- Able to be the lead microbiologist for sterile processing and assessment to meet the GMP requirements
- 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.
- Direct experience with sterile injectable and proven success regulatory inspections
- Able to be the Global Leader for Sterility Assurance and Cross Contaminations controls
- 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 required. .
- Previous FDA direct experience 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.