Regulatory Specialist and Consultant

Reguliance LLC is a US Regulatory Affairs consulting firm seeking to hire a full-time US Regulatory Specialist and Consultant with:

- Knowledge and expertise in the following areas: Pharmaceutical, Bio-pharmaceutical, and combination products

- Practical hands-on experience in the content and format, submission and maintenance of: Orphan Drug Designations, INDs, BLAs, NDAs, ANDAs, DMFs, Suitability/Citizen Petitions, Self-ID, Establishment Registration, and Drug Listing

- Commanding expertise in: FDA regulations and guidances, CMC, nonclinical, clinical PI through PIII, Pharmacovigilance, preparing for and conducting FDA meetings

- Exceptional communication skills in written, verbal, and presentations formats

The successful candidate will assist Reguliance clients in managing their US FDA development projects.

Specific Duties/Responsibilities:

- Communicate and interpret FDA activities, regulations, policies and guidances for Reguliance clients
- Provide input on the preparation, organization, and submission of FDA meeting requests, as well as manage and attend FDA meetings
- Provide input on the preparation, organization, and submission of INDs, BLAs, NDAs, ANDAs, DMFs, Orphan Drug Applications, and all documents/submissions critical to product life cycle
- Communicate with FDA relating to regulatory matters on behalf of clients
- Create and manage project proposals, legal agreements, schedules, budgets, and SOPs
- Present at Reguliance sponsored seminars

Qualifications:

- Must be a US citizen or US Permanent Resident
- Must be located in the US Eastern time zone (EST)
- Must have valid passport for International travel
- Degree in biological sciences, chemistry, pharmacology, pharmacy, nursing, medicine or related scientific discipline is required
- Minimum of 7 years prior US FDA regulatory affairs experience in pharmaceuticals or biologics
- Extensive experience in Orphan Drug, IND, BLA, NDA, ANDA, or DMF submissions
- Competency working in CTD and eCTD format
- Experience coordinating regulatory documents, participants, etc. for FDA meetings
- Familiarity with documents required and/or normally included in FDA submissions

- Comprehensive knowledge of and ability to interpret FDA regulations, policies and guidances
- Strong organizational skills and high level of attention to detail, with the ability to coordinate and independently manage multiple and diverse projects simultaneously
- Ability to effectively interact directly, and in a team environment, with national and international clients, Reguliance staff, and 3rd Party Contractors
- Excellent written, verbal and presentation communication skills
- Meet with clients and conduct regulatory presentations in US and non-US locations
- Regulatory Affairs Professionals Society Certification (RAC) designation preferred Proficiency in Microsoft Office programs
- Experience with medical devices or prior Seminar presentation experience a plus

Applicants must meet the qualifications above to be considered for this position.

Reguliance is located in Burlington, Vermont – home to beautiful Lake Champlain, University of Vermont, Bernie Sanders, the slogan “Vermont – keep it weird!”, lots of cows and skiing, boating, hiking, fishing, hunting, and other outdoor sports. The candidate may work remotely.

We offer a low-key work environment, a competitive salary and benefits package. This is a growth position with opportunity to be a key member of our consulting team.

Reguliance provides equal employment opportunity to all persons regardless of age, color, national origin, race, religion, creed, gender, sex, sexual orientation, gender identity and expression, marital status, disability or protected veteran status, or any other characteristic protected by federal, state or local law.

To apply, please submit resume and cover letter to ymcgee@reguliance.com.