#19001R

Job Ad

Director of Regulatory Affairs

The Director of Regulatory Affairs will be responsible for the leadership and oversight of the Regulatory Affairs Department and staff of six to ten professionals. The Director will be responsible for the day-to-day planning and oversight of all consulting assignments and client deliverables from CBR Regulatory staff as well as development and maintenance of CBR Regulatory Systems. This position has a career progression to Senior Director of Regulatory Affairs and Vice President of Regulatory Affairs.

Additional Job Requirements:

- Advanced degree in a science, toxicology, pharmacology, engineering, or related field – preferred
- 5 - 10 years of experience in the FDA regulated industry for biologics and small molecules
- Experience with Devices – preferred
- Some supervisory experience is required
- Knowledge and understanding of FDA regulations, ICH guidelines, and global industry standards for the development of regulated investigational products
- Skills in leading complex technical programs and managing multiple projects simultaneously
- Ability to work collaboratively with CBR staff and clients
- Ability to provide clear, concise oral and written communications
- Comply with and support all company policies and procedures, safety and security rules, and standards of professionalism
- Maintain a relevant professional membership (ISPE, PDA, RAPS, RMRAS, etc.)
- Maintain company confidentiality
- Valid driver's license and insurance
- Maintain a valid passport

About CBR International

With offices in Boulder, Denver, Fort Collins, Atlanta, and Berlin (CBR Biotech Strategies), **CBR International** is a global regulatory development company providing comprehensive product development services to the biotechnology and pharmaceutical industries worldwide. Our expert staff is knowledgeable in an all-encompassing range of indications for drugs, novel antibodies, recombinant protein therapeutics, small molecules, vaccines, cell therapy, medical devices, and combination products throughout all phases of program development (Phases I - IV) and commercialization.

We value our amazing staff of professionals, as well as our clients, who together help to bring cutting-edge science and innovative biotechnology products to populations around the world. We ***are*** making a difference. CBR International has a mission to work with local and global partners to develop strategies that result in achieving successful product, clinical, and regulatory programs. We are committed to creating an environment of team-building, learning, and professional development, which enables us to better advance long-term goals for CBR clients and staff.

Why CBR International is the Fit for You

Ask yourself this: Do you enjoy challenging yourself intellectually? Learning about the latest and greatest technologies that science and biotech have to offer? How about traveling, seeing the world, and learning about global pharmaceutical development? CBR offers competitive salaries and great benefits, including: medical, dental, vision, matching 401K, company-sponsored events, wellness benefits, corporate health club membership, professional development opportunities, professional memberships, and so much more.

Interested in Applying

Please send a resume and cover letter to HR@cbrintl.com and include reference number #19001R. We are excited to hear from you!