Regulatory Affairs Scientist/Sr. Regulatory Affairs Scientist/Manager/Sr Manager

Hengrui Therapeutics, Inc. is recruiting a Regulatory Affairs Scientist/Sr. Regulatory Affairs Scientist/Manager/Sr Manager. The office location is Princeton, NJ, and due to COVID-19 considerations, until the office re-opens the position is WFH.

Hengrui Therapeutics, is a biotechnology startup, focusing on different stage including late phase/NDA/BLA clinical development of innovative therapeutics solutions in areas of major unmet medical needs, such as oncology, immunology/inflammation, metabolic disorders, and other therapeutic areas. We offer abundant opportunities for motivated pharmaceutical professionals to pursue their scientific/clinical interests, make an impact and maximize their growth potential.

Job Description:

The RA Scientist/Sr. RA Scientist will have the responsibility for driving regulatory operations, participating in regulatory project management, and developing key aspects of US Regulatory science and strategy at HTI, in collaboration with multiple stakeholders across the global enterprise.

Responsibilities

1. Assess and evaluate submissions, according to type, regulatory authority, and country
2. Lead regulatory IND/NDA submission for tactical support and input to the regulatory and clinical action roadmaps. Provide submission planning support on project teams
3. Ensure all documents comply with US and global regulations and internal standards prior to acceptance into publishing environment
4. Participate in development of the US and global regulatory strategy for assigned products in Oncology and other serious diseases, accounting for company objectives and relevant guidance
5. Lead interactions with FDA for assigned projects.
6. Anticipate trends and changes in the US regulatory environment and assess impact on development and registration strategies
7. Build positive relationships with FDA and other regulatory authorities
8. Review, submit and write assigned dossiers to health authorities
9. Ensure early clinical strategic input during clinical development to Technical and Clinical Development teams
10. Build and maintain a collaborative team relationship across functional areas, including Clinical, Safety, Manufacturing, Pharmacology and Toxicology to drive early and late development
11. Lead dossier submissions collaboratively with other members of Regulatory Operations for submission of dossiers, meeting packages, and special requests such as Orphan Drug Designation, Fast Track, Breakthrough Therapy, Scientific Advice, or other requests to accelerate drug development.
12. Ensure quality and compliance in all activities

PharmD or PhD in related field (biological science) or Bachelor's or Master's degree with at least 2 years of relevant industry experience

- Experience with IND/CTA or other submissions a plus
- Experience with PMA/MAA/NDA/BLA submissions a plus

- Solid knowledge and understanding or willingness to learn complex medical and scientific subject matter
- Willingness to learn and master regulations including regulatory submissions in eCTD format
- Excellent communication skills, including command of spoken and written English
- Sensitivity for multicultural/multinational environment and understanding of the global pharmaceutical development process
- Excellent operational skills including planning and organizing
- Ability to work as a team player on project teams, with an understanding of timelines for meeting deliverables and project requirements
- Unquestionable ethics, professional integrity, and personal values

We strive to offer a positive atmosphere in our start-up office. We understand the importance of balance and flexibility in our work environment and offer industry competitive benefits.

***Please include salary requirements when submitting CV/Resume to:**
hr@hengruitx.com