HENGRUI THERAPEUTICS, INC.
506 Carnegie Center, Suite 102, Princeton, NJ 08540

Director/Senior Director, Regulatory Affairs

Hengrui Therapeutics, Inc. is recruiting a Director, Regulatory Affairs, located in Princeton, NJ.

Hengrui Therapeutics, Inc. (HTI) is a biotechnology startup, focusing on clinical development of innovative therapeutic solutions in areas of major unmet medical needs, such as oncology, immunology, cardiovascular, metabolic disorders, and neuroscience. We offer abundant opportunities for motivated pharmaceutical professionals to pursue their scientific/clinical interests, make an impact and maximize their growth potential.

The ***Director, Regulatory Affairs*** will be responsible for managing all regulatory aspects (Clinical, CMC) of clinical development of multiple innovative drugs in different therapeutic areas. The position level is dependent on experience and qualifications.

Major Responsibilities

- Develop and implement global regulatory strategies for IND/NDA/BLA applications.
- Provide regulatory guidance and scientific advice to cross-functional international project teams to ensure early consideration of regulatory and clinical requirements, as well as alignment on regulatory plans and strategies.
- Interface with cross-functional teams (CMC, Nonclinical, Clinical) to define contributions of required documents for regulatory submissions.
- Collect, review and revise study reports and documentation to ensure high-quality preparation of applications (IND, CTA, BLA, NDA, etc.) in compliance with FDA and other global health authority requirements.
- Interact with regulatory agencies, coordinate the preparation of responses to questions and inquiries from FDA and other health authorities.
- Serve as primary liaison with regulatory authorities, including overseeing the writing of meeting materials, leading the preparation for meetings with regulatory agencies, and ensuring appropriate follow-up.
- Monitor and maintain all regulatory activities to ensure compliance with relevant regulatory requirements, including but not limited to, protocol and information amendments, clinical study reports (CSRs), pediatric study plans, annual reports and safety reports to support clinical development in the US, EU, Canada, and other countries as necessary.
- Ensure relevant US and international regulatory laws, regulations and guidance, as well as internal policies and procedures are followed to ensure regulatory compliance is maintained.

Qualifications

- Requires a Master's degree in life science or related discipline, PhD preferred.
- 10+ years of pharmaceutical industry experience required. At least 5 years of regulatory affairs with experience associated with global submissions.
- Experience with the research and development of oncology drugs is highly desirable.

- Ability to speak Chinese is a plus.

Required Knowledge and Abilities

- Excellent knowledge of global regulatory requirements and processes and filing experience (IND, CTA, NDA, BLA).
- Extensive experience working with CRO's.
- Strong verbal and written communication skills are essential.
- Excellent organizational and analytical skills. Detail oriented and a great ability to support multiple projects in a timeline-driven environment.
- Exceptional interpersonal skills with the ability to influence others in a positive and effective manner.
- Demonstrated leadership and people management skills in a matrix organization.

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