Director / Senior Director Regulatory Affairs (f/m/d)

Position Location: Ladenburg / home based in any EU member state
Permanent position in full-time or part time (approx. FTE 0,8)

Heidelberg Pharma AG is a biopharmaceutical company based in Ladenburg near Heidelberg. Heidelberg Pharma AG is listed at the Frankfurt Stock Exchange in the Regulated Market/Prime Standard. Our main goal is to develop drugs against cancer. Our focus is primarily on the ongoing development of our innovative ATAC (Antibody Targeted Amanitin Conjugate – ATAC) platform technology based on the active ingredient Amanitin. Based on this platform, the first drug candidate will enter clinical development in 2021 and we are in the process of expanding our pipeline to deliver several development candidates and start new clinical programs through the next few years. To be successful strong interactions with national and international regulatory agencies are required. The goal of Heidelberg Pharma is to become a leader in the ADC space.

The function holder will act as the global regulatory lead on Heidelberg Pharma's development programs, providing regulatory guidance and oversight. He/ She will be responsible for management of all regulatory activities, including management of regulatory service providers. He/ She will be responsible for the development and execution of regulatory strategies including submission strategies, to ensure the expeditious review and approval of clinical trials. Further the function holder will manage and coordinate the preparation of all required regulatory documentation. He/ She leads, influences, and defends the regulatory position in regulatory agency interactions and acts as regulatory Subject Matter Expert when reviewing clinical documents, reports and all types of regulatory documentation (quality, safety, efficacy, and labeling) throughout development.

Duties & Responsibilities:

- Carry out a full review of current status of all regulatory matters and support the Board of Directors to define the company's future regulatory strategy.
- Act as the regulatory representative on and provide strategic regulatory guidance to project teams.
- Management of, and collaboration with, regulatory service providers for regulatory submissions.
- Lead the planning and preparation of all preclinical and clinical regulatory submissions (e.g., Investigational New Drug Applications, Clinical Trial Applications, Orphan Drug Applications, Pediatric Investigational Plans, Scientific Advice requests, etc.)
- Establish and manage regulatory timelines.
- Responsible for submitting high quality regulatory documents required to obtain successful outcomes. Prepare meeting requests and briefing documents; make

sure a team is well prepared for meetings/teleconferences with regulatory agencies.
- Coordinate and prepare responses to Regulatory Agency requests
- Prepare regulatory development plans for all projects.
- Develop and maintain regulatory knowledge.
- Serve as an interface with CMC, nonclinical and clinical research personnel and help keep them informed of new regulations, standards, policies, and guidance issued by regulatory authorities.
- Communicate the company's position to internal and external stakeholders.
- Assist in the development and maintenance of departmental processes, policies, SOPs and associated documents.

Qualifications:

- Science degree or equivalent qualification: Chemistry, pharmacy, biochemistry, or related to degree or above level.
- Minimum of 8 years' experience in a biotech/pharmaceutical research environment, including 5+ years in Regulatory Affairs.
- Experience in DE/EU/US centralized regulatory submissions and associated activities, including PEI/BfArM/EMA/FDA liaison.
- A strategic regulatory mind-set.
- Experience in oncology and working with biologic products is preferred.
- Team player, who can handle multiple tasks simultaneously in a fast-growing company.
- Requires a highly motivated, resourceful individual who can set goals, shift priorities, work independently and collaborate effectively with project teams.
- Ability to manage complex negotiations with Regulatory Authorities.
- Excellent verbal and written communication skills, including a positive and professional attitude.
- Fluent Business and/or Medical English and good command of German language (each spoken and written).
- Ability to meet short deadlines in a dynamic environment, including the rapid translation of operational strategies into clear objectives and deliverables.

What we offer:

We offer the opportunity to work in a professional team to research and develop cancer drugs. It is important to us that people have the opportunity to develop their potential and thus contribute to the success of our company. We will offer a challenging and diverse field of work within a committed team as well as a competitive salary.

Have we sparked your interest?

Please send your detailed application preferably by email to our personnel department to

jobs@hdpharma.com

Please specify your expected income and earliest possible starting date.

Only together can we slow down the global spread of COVID-19 and protect our society. Therefore, the first round of our interviews will be conducted via telephone or video. We strongly encourage you to continue to apply for a job with us and look forward to getting in touch with you!

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