Immutep is hiring:

Regulatory Affairs Associate (m/f/d)

Company: *We are Immutep, an emerging international biotechnology company developing immunotherapeutic products for cancer and autoimmune diseases. With operations based in Australia, USA, Germany and France, Immutep is dedicated to bringing innovative treatment options to market for patients. The company is publicly traded on the ASX and NASDAQ.*

Location: Berlin, Germany; office based, 75-100 % negotiable

Summary: As a result of continuous progress in our projects we want to expand our team and therefore seek a Regulatory Affairs Associate. You will work closely with Regulatory Affairs Managers (RAMs) and other project team members to support the development and maintenance of our clinical trial program within a global environment. Furthermore, we seek administrative support in organizing scientific advice meetings with multiple agencies around the world. This implies the supporting of national and international projects under consideration of local laws, international guidelines (ICH GCP) and applicable SOPs.

Job description:

- Coordinate internally and support the preparation and submission of regulatory agency applications, reports, or correspondence
- Coordinate internally and support the company interaction with regulatory authorities, e.g. scientific advice, designations, expedited programs, waivers etc.
- Responsible for timelines and document finalization (formal point of view) needed in regulatory affairs (RA) processes
- Support other departments preparing documents required for regulatory processes (QC checks, TC versions, formatting)
- Responsible for filing RA documents, digital and physical for projects assigned
- Communicate with external partners to support our regulatory affairs projects (e.g. consultants, subcontractors, clinical research organizations)
- Support product development and lifecycle, due diligence processes and internal and external company communication with regulatory input
- Responsible for the compilation of submission/scientific advice packages as assigned

Skills/Experiences/Qualifications:

- Natural/ life sciences background
- Knowledge and experience in relevant legislation and international guidelines (ICH-GCP) for the performance of clinical research projects
- Minimum 2 years' experience in Regulatory Affairs in clinical development is essential
- Required previous experience/good knowledge in the coordination of complex submissions (multiple connected documents) and interaction with agencies
- Proficiency in English (written and spoken) is essential. German and/or a second European language is a plus
- Proficiency of standard software (Word, Excel, Outlook, Power Point)
- Experience in oncology, immune oncology is a plus
- Medical writing skills are a plus
- General understanding of R&D processes

Job expectations:

- Multifunctional interesting tasks in the emerging field of immune therapeutics
- Be part of the development of a "first in class" drug
- Highly motivated and energetic international team
- Competitive compensation

Expected start date:

- 1st February 2022

The contract will be limited to March 2023 initially but can be turned into a permanent position end of 2022.

If you are interested in this challenging career opportunity, please send your CV, certificate of employments, salary expectations, application letter and your earliest possible entry date to the following e-mail address (confidentiality is of course guaranteed):

hr-germany@immutep.com

In case of questions you are welcome to contact us via email.

privacy statement for applicants