Immutep is hiring:

Clinical Research Quality Assurance Position (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 develop innovative treatment options. The company is publicly traded on the ASX and NASDAQ.

Location:

Berlin, Germany; office and home based, (part time 50 %)

Summary:

As a result of continuous progress in our projects we want to expand our team and therefore seek an additional Quality Assurance position. You will work closely with the lead Quality Assurance Manager to support the development and maintenance of the quality management system to ensure quality throughout all stages of the projects managed by Immutep under the scope of the guidelines on Good clinical practice (GCP), Good manufacturing practice (GMP) and Good Laboratory Practice (GLP), while being independent of the operative management of those projects.

Job description:

- SOP system review: SOP quality checks, periodic review and maintenance of SOPs and templates; control of templates regarding regulatory conformance
- Maintaining the SOP log, all original signed current SOPs, archived SOPs and initiating the scheduled SOP review procedure
- Training procedure: perform and support SOP trainings, maintain overview of training records ensuring that relevant staff is properly qualified and (re)trained in the use of SOPs and other controlled documents, maintain training matrix
- Audits: preparation of annual audit schedule, support and preparation of project audit plans, as well as external/internal GxP audits and GCP site audits
- Prepare /review vendor qualification documents like qualification questionnaires, risk assessments and qualification summaries, maintain list of vendors
- Quality Risk Management: review of potential risk information, initiation and monitoring of risk assessment
- Issue management and CAPA follow up
- Supporting complaint management and recalls
- Serve as main contact for quality related activities, clinical project specific QA guidance, clinical project document review

Skills/Experiences/Qualifications:

- Natural/ life sciences background
- Profound understanding of quality assurance tasks in the clinical trials environment **is a must**
- Profound knowledge and experience in relevant legislation and international guidelines (ICH-GCP (R2), CTR 536/2014)
- Knowledge of other GxP areas would be a plus
- Minimum 3 years of experience in Quality Management in clinical development

- Refined colloquial and correspondence skills in English (written and spoken) is essential
- Very good German (written and spoken) is a plus
- Proficiency of standard software (Word, Excel, Outlook, Power Point)
- Experience in oncology/ autoimmune diseases is a plus

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:

- As soon as available

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

Privacy Statement for Applicants