APEIRON is a privately-held European biotech company based in Vienna, Austria, focused on the discovery and development of novel cancer immunotherapies. APEIRON received EU marketing approval for APN311 (Dinutuximab beta, Qarziba®) in May 2017 for the treatment of pediatric neuroblastoma patients and out-licensed global, exclusive rights for this product to EUSA Pharma Ltd. APEIRON now leverages its proprietary master checkpoint blockade mechanism to enable the human body's natural defense mechanisms to fight the tumor. APEIRON's clinical lead program APN401 is a first-inclass autologous cellular therapy which enhances anti-tumor immunity by inhibiting the intracellular master checkpoint, Cbl-b. APEIRON's projects and technologies are bolstered by a strong patent portfolio. APEIRON's development expertise is validated through partnerships with leading pharmaceutical companies and academic institutions.

We are searching for an enthusiastic

Clinical Study Manager

Position Objective:

Provide mid-level operational oversight and leadership for a of US based early stage program in Oncology

Responsibilities:

- The Clinical Study Manager (CSM), under the direction of the Clinical Development Head, is accountable for the day to day planning, execution and reporting from site feasibility up to and including study site close-out of APEIRON's global APN401 clinical program in collaboration with our global contract research organization (CRO)
- The CSM is the single point of contact and APEIRON local study team lead for the assigned studies. The CSM is responsible for assuring aligned communication, execution and progress of the studies with the external CRO and US study sites. These responsibilities include selection/initiation/monitoring, working with local site monitors, study budgets/contracts, review of the scope of work for external vendors, study timelines and conduct, clinical supplies, database locks, manage study close out activities and implementation of SOPs.
- The CSM is accountable to communicate with and support relationships with the clinical research staff in the US investigational sites in close coordination with the external CRO and third-party vendors
- Work closely with other key support areas including internal and external functions including CMC, Medical Writing, Regulatory Affairs, Project Management, Data Management, and other allied support functions

- Ensures that study start-up activities are conducted and completed on time, including preparation of IRB/EC submission packages, review of Informed Consent Forms
- Drives the conduct of the study (tracks status, maintains study level reporting systems, oversees forecasts, progress, and mitigation plans), to ensure all study operational aspects are on track.
- The CSM will assist in site selection, investigator meetings and site initiation visits. For ongoing clinical trials, this individual will review all incoming clinical data in real time including patient screening results, PK/PD data, adverse events and other study endpoints and will perform medical review activities.
- Ensure the efficient collection and support the review of safety, efficacy, PK/PD, biomarker, interim analyses and proof-of-concept data for early phase clinical trials with internal matrix subteams (CMC, Biomarker) and external stakeholders while maintaining compliance with Good Clinical Practice (GCP) guidelines

Minimum Requirements:

- Candidate must have a minimum Bachelor or Master in Science degree
- Minimum of five to ten years' Phase 1, 2 and/or 3 experience in clinical drug development in a role that oversees the monitoring of clinical trials (Pharma, Biotech and/or CRO required)
- Understanding of all aspects of clinical drug development with particular emphasis on monitoring and study execution
- Thorough understanding of the international aspects of drug development process, including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMEA), local/National Health Authorities regulations
- Scientific and/or laboratory experience preferred but not required
- Oncology therapeutic area experience strongly preferred but not required
- Prior clinical trial experience in cell therapy (CAR T, TILs, CRISPR) and RNAi therapeutics highly desirable, NBEs and/or oral NCEs required
- Previous conduct and support of global oncology clinical development studies implementing adaptive clinical trial designs, master protocols (umbrella, basket, platform) and successful Phase 1/2 starts preferred
- Effective oral and written communication skills (German and English fluency) to influence, inform and guide an international multi-center operational team

Professional & Personal Skills:

- Strong interpersonal skills with an outgoing, collaborative nature
- Ability to work in multidisciplinary teams
- Creative, innovative and a self-starter
- A dynamic, energetic doer, with the ability to focus and complete
- Fosters development of common vision
- Leads courageously – addresses difficult issues, takes a stand
- Influences others - gains support and commitment from others
- Fosters teamwork - builds effective teams committed to goals
- Motivates others – encourages and empowers people to excel
- Coaches and develops others – gives timely and specific feedback
- Strong integrity, both operationally, scientifically and professionally

We offer:

- To be part of a successful and growing company
- Exciting projects and international activities
- Self-responsible and autonomous work environment
- Flexible and/or part-time working hours position possible

If you enjoy working in a dynamic, motivated and international team with an open and friendly corporate culture we are looking forward to receiving your cover letter and curriculum vitae.

For the position we offer at least an annual gross salary of € 70.000, -. The actual remuneration package will be based on your professional experience, qualification and skills. Increased pay is possible.

Contact:
Human Resources
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