APEIRON Biologics is a privately held European biotech company based in Vienna, Austria, focused on the discovery and development of treatments for respiratory diseases and novel cancer immunotherapies. APN01 (alunacedase alfa; rhsACE2), a soluble recombinant version of the SARS-CoV-2 cell entry receptor ACE2, has completed a double blind, placebo-controlled Phase 2 trial in patients with COVID-19 in Europe and Russia.
APEIRON received EU marketing approval for APN311 (Dinutuximab beta, Qarziba®) in 2017 for the treatment of pediatric neuroblastoma patients and out-licensed global, exclusive rights for this product to EUSA Pharma Ltd.
APN401´s proprietary process brings in a paradigm change in cancer treatment to fight hematological and solid tumors. The clinical program is a first-in-class ambulatory autologous cellular therapy to strengthen immune reactivity via an intracellular master checkpoint inhibitor, Cbl-b.
APEIRON Biologics´ projects and technologies are based on a strong patent portfolio and partnerships with leading pharmaceutical companies and academic institutions.

For our office **in Vienna** we are searching for an enthusiastic

Head of Clinical Operations (fulltime)

Position Objective:

Lead a motivated team of Clinical Project Managers in the area of respiratory disease and oncology. Responsible for assuring aligned communication, execution and progress of the studies with the external CRO and 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.

Responsibilities:

- Act as Clinical Program Lead in selected projects, including preparation and planning of clinical studies
- Project controlling (dates, cost, reporting, regular meetings, milestones)
- Collaborating with and managing external partners (vendors, clinical research centers)
- Planning, implementation, coordination and supervision of clinical trials
- Organization and management of study relevant documents (from concept to archival)
- Implementation of audits from external partners and clinical study sites
- Communication with the competent authorities and ethics committees
- Presentation of study results in the context of meetings and scientific conferences
- Authoring or co-authoring of internal communication documents (i.e. project updates)
- Preparation of clinical submission documents for a regulatory audience, within a team environment and ensuring process, content, and submission/document planning expertise
- Creation and maintenance of MSOPs, SOPs and forms and further training, including development of appropriate workflows as relevant to clinical activities
- Conduct of internal trainings
- Ensuring critical review and interpretation of clinical efficacy and safety data
- Review and comment on documents in clinical programs (e.g. protocols, IBs)
- Playing an active role in improvement of processes and implementation of agreed improvement steps

Minimum Requirements:

- Candidate must have a minimum Master's degree or PhD in life sciences
- 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/EMA), local/National Health Authorities regulations
- Scientific and/or laboratory experience preferred but not required
- Oncology therapeutic area experience strongly preferred but not 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 working hours position

If you enjoy working in a highly motivated and international team with an open and friendly corporate culture, we are looking forward to receiving your application (incl. Curriculum vitæ and photo).
For the position we offer at least an annual gross salary of EUR 70.000,- on a full time basis. The actual remuneration package will be based on your professional experience, qualification and skills. Increased pay is possible.

For more insights into APEIRON Biologics please go to www.apeiron-biologics.com
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1030 Vienna, Campus-Vienna-Biocenter 5

Information on the handling of your personal data can be found at:
https://www.apeiron-biologics.com/privacy-policy/