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-in-class 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.

For the manufacturing of rhACE2 we are searching for an enthusiastic

**Head of External Manufacturing and CMC for APN01/Covid-19**

with immediate availability

**Position Objective:**

The Head of External Manufacturing is responsible for management of the selected Contract Manufacturing Organizations to guarantee the continuous supply of clinical studies with IMP and to support regulatory and clinical department for regulatory filings.

You have to fulfill your tasks in consideration of available resources and synergies and in line with applicable laws and guidelines on pharmaceutical quality systems.

**Minimum Requirements:**

- Candidate must have an University degree in life sciences
- Pharmaceutical CMC expert with at least 8 to 10 years’ experience in biopharmaceutical development and cGMP manufacture
- Previous work experience in a cGMP regulated environment (biopharmaceutical production and quality control)
- Experience in managing external collaborators

**Responsibilities:**

- Supervise all employees of the External Manufacturing (GMP) department
- Selection of suitable Contract Manufacturing Organizations and Contract analytical labs
- Transfer of process and production technology and of analytical methods and validation protocols from development to a qualified supplier and between qualified suppliers
- Monitor the successful implementation and develop process improvement programs or preventive actions
- Determine test plan and specification for release of drug substance and drug product together with other relevant functions (quality, etc.)
- Establish response to CMC related questions of regulatory bodies
- Coordinate the supply chain (incl. logistic of shipment and inventory) and disposition of drug substances, drug products
- Assure that all manufacturing operations (drug substance and drug product) are in compliance with applicable GMP regulations
- Support the legal department by reviewing and negotiating Contracts, Contract vendor Quality Agreements, Technical Agreements and Supply Agreements
- Review and approval of documents from CMOs (qualification/validation documents, specifications, transfer protocols, batch records, stability protocol, ...)
- Supervision of production through site visits at CMOs if required
- Cost center management
- Support development teams as GMP representative
- Support regulatory affairs function with production documentation for successful submissions, assisting in drafting and reviewing of CTD Module 2 & 3 (Quality) documents in preparation for submissions to regulatory authorities
- Support the clinical department in their technical discussion with their external partners (e.g. CROs, doctors; logistic of product supply, labeling/packaging)

**Professional & Personal Skills:**
- Strong interpersonal skills with an outgoing, collaborative nature
- Ability to work in multidisciplinary teams
- Strong integrity, both operationally, scientifically and professionally
- Creative, innovative and a self-starter
- Committed team player who is able to cope with pressure
- Leads courageously – addresses difficult issues, takes a stand
- Motivates others – encourages and empowers people to excel
- Hands-on approach

**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 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 € 75,000, -. The actual remuneration package will be based on your professional experience, qualification and skills. Increased pay is possible.
Contact: Human Resources, Elena Pretterebrner, Email: elena.pretterebrner@apeiron-biologics.com
1030 Vienna, Campus-Vienna-Biocenter 5