APEIRON Biologics AG is a European private biotechnology company based in Vienna that specializes in the discovery, development and commercialization of novel immunotherapies for cancer and respiratory diseases. APEIRON's APN01/alunacadase alfa (rhsACE2) is undergoing a Phase II clinical trial for the treatment of Covid-19. APEIRON has an approved product on the market, Qarziba® for the treatment of pediatric neuroblastoma patients which is distributed by EUSA Pharma Ltd.

APEIRON's clinical program APN401 is a first-in-class autologous cell therapy to strengthen immune reactivity via targeting the intra-cellular master checkpoint, Cbl-b. APEIRON's project and technologies are based on a strong patent portfolio and partnerships with leading pharmaceutical companies and academic institutions.

To strengthen our *External Manufacturing Team* we are searching for an

External Manufacturing/CMC Manager
(minimum 30 hours/week)

Position Objective:

The *External Manufacturing/CMC Manager* is responsible for the management of contract manufacturing organizations and contract analytical laboratories to guarantee the continuous supply of clinical studies with IMP and to support regulatory and clinical department for regulatory filings.

Minimum Requirements:

- Candidate must have a University degree with life science focus
- At least 3 years' experience in a GMP regulated environment (biopharmaceutical production and/or quality control)
- Experience in managing external collaborators

Responsibilities:

- Selection of suitable Contract Manufacturing Organizations and contract analytical labs
- Determine critical process parameters, critical quality attributes and batch release and stability specifications in collaboration with other relevant functions
- Transfer of biopharmaceutical processes and analytical methods from development to or between qualified CMOs
- Review and approval of documents from CMOs
- Monitor successful process implementation and develop continuous improvement programs
- Coordinate the supply chain (incl. logistic of shipment and inventory) of drug substances, drug products
- Support regulatory affairs function with production documentation and assist in drafting and reviewing of CTD Module 2 & 3
- Establish response to CMC-related questions of regulatory bodies
- Support the legal department by reviewing and negotiating supplier contracts

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
- Hands-on approach
- Proficiency in German and English

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 (with core time)
- Possibility to work from home

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 application (incl. Curriculum vitae and photo).

For the position we offer at least an annual gross salary of € 56.000,- (on full time basis). The actual remuneration package will be based on your professional experience, qualification and skills.
Contact: Head of HR, Elena Pretterebner
Email: jobs@apeiron-biologics.com
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