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.

Project/Regulatory Manager

(Full-time)

Position Objective:

To strengthen our development activities for our **main office in Vienna** we are looking for a committed and independent Project Manager with a strong **regulatory background**.

Professional & Personal Skills:

- Candidate must have a University degree in life sciences, preferably PhD
- At least 5 years of professional experience in project management and regulatory affairs
- Excellent German and English skills (at least C-Level)
- Excellent technical understanding and G(x)P knowledge
- Experience in submitting applications for approval as well as in creating and maintaining CTDs and eCTDs
- Independent, related, cautious and structured way of working
- Creative, solution-orientated and a quick thinker, excellent organizational communication skills with a hands-on approach

Responsibilities:

- Organization, coordination and management of product development and regulatory strategies
- Definition and distribution of work packages with realistic time and milestone plans including escalation management
- Documentation of the project progress and the project history as a basis for decision-making for the steering team
- Preparation and follow-up of project coordination meetings with internal and external stakeholders
- Support regulatory strategies and interact with external consultants
- Planning, preparation and submission of approval applications (EU/USA)
- Coordination of national and international drug approval and registration procedures

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
- Possibility to work from home

If you enjoy working in a motivated team with an open and friendly corporate culture we are looking forward to receiving your application (incl. cover letter and curriculum vitæ with photo). Please note that we will focus our interview process based on a willingness to work in Vienna.

For the position we offer at least an annual gross salary of EUR 80.000,-. The actual remuneration package will be based on your professional experience, qualification and skills. Increased pay is possible.
Contact: Head of HR, Elena Pretterebner
Email: jobs@apeiron-biologics.com
APEIRON Biologics AG, Campus-Vienna-Biocenter 5, 1030 Vienna