Head of Pre-Clinical Development (m/f/d) – Full-time

Origimm Biotechnology GmbH is an international early-stage biotech company located in **Vienna** with a dedicated and highly motivated small team. With the development of new vaccines, immune therapies and skin health products, we strive to improve the quality of life of patients by improving skin health and preventing or treating skin microbiome-associated disease. We stand for innovation and honesty and always demand the highest standards from ourselves and our products out of respect for the patients.

To support our CEO in the time-intense area of product development, we are looking for a full-time **Head of Pre-Clinical Development (m/f/d)**, who will be responsible for bringing company's pre-clinical and clinical candidates from research through the development process. This includes pre-clinical activities supporting clinical studies, and preclinical assays and studies, as well as project management activities, and preferably also CMC (Chemistry, Manufacturing and Controls) activities.
The HPCD will be required to work in close corporation with the CEO/CSO as well as the Head of Clinical Development (HCD) and the Head of Innovation Skin Health (HISH).
We are seeking the best in their profession to match our high standards, and in return, we provide a motivating and supportive work environment.

We offer

- Professional and pleasant working atmosphere
- Work surrounding fostering individual creativity
- Working conditions under highest ethical standards and concern for human health
- Highly innovative scientific work environment based on mutual trust and support
- Very engaging, responsible and diversified position
- Amenities and specifics of a small early-stage company, attractive fringe benefits
- Flexible working hours
- Possibility to bring new products from pipeline to the development stage

Responsibilities

- Pro-actively leading the development of products exiting the product design & concept phase until and through clinical development, in close cooperation with the CEO/CSO, HCD, and HISH
- Leading the respective project teams including people development as well as daily management tasks
- Coordination, supervision and evaluation of assay development, assay set-up and analytical studies
- Overall responsibility and accountability for all non-clinical and pre-clinical activities required for the product development
- Overall responsibility for all drug substance and drug product activities from preclinical development through clinical supplies
- Identification, selection and management of Contract Manufacturing Organizations (CMOs) for process optimization, cGMP manufacture and supply of Drug Substance (API) and Drug Product (DP) in support of clinical programs
- Management of supply chain and logistics in support of clinical studies
- Preparation and review of cGMP batch records, CMC regulatory and Quality documents, including IMPD

- Product development activities: vaccine candidates production and characterization; development of methods and analytical studies; in vivo studies (animal models); non-clinical and pre-clinical activities required for product development and clinical trial approval
- Managing design, generation and selection of monoclonal antibodies in collaboration with external partners
- Preparation of research grant applications and reports to funding agencies
- Obtaining operational permits, creating, and approving laboratory documentation, including SOPs
- Supporting company strategy, structure and culture in alignment with our company purpose and values

Qualifications and Professional Background

- Degree in life sciences (MSc or PhD)
- At least 10 years of experience in leading departments and teams
- Proven track record of managing pre-clinical development phase of biologics; especially vaccines and monoclonal antibodies
- Track record in providing necessary support for preparation and execution of clinical trials
- Experience and successful track record in writing research grants, project plans and progress reports
- Experience in auditing external service sites according to cGMP and successfully managing multiple contract research organizations (CROs)
- Significant experience in dealing with regulatory authorities and knowledge of current guidelines
- Ability to work in a highly cross-functional organization and keep track of details without losing the big picture
- High level of project management competences
- Experienced leader and manager with the ability to handle individual personalities and develop highly effective teams
- Ability to represent the company towards partners, investors and authorities
- High level of communication and presentation skills
- Highly reliable and responsible personality
- Collaborative work attitude; adaptable and flexible personality
- Outgoing and inspiring personality
- Willing to travel on behalf of the company
- Professional business English knowledge and at least basic fluency in German

The minimum salary we offer for this position is € 5.000,-- gross per month for full-time. The actual salary will depend on relevant experience and qualification of the designated candidate and will be negotiated at the time of the job offer. We explicitly encourage female candidates to apply for this position.

Does our description meet your expectations concerning your next career step? Then please send us your CV plus an informative motivation letter and convince us that you are the best candidate for this position. We are looking forward to receiving your application at recruiting@origimm.com.