Polyneuron Pharmaceuticals AG
Hochbergerstrasse 60C
CH-4057 Basel

Polyneuron is a fast-growing Basel-based biotechnology company active in the area of autoimmune disease treatments. The company was founded in 2014 as a spinout company from the University of Basel to develop novel treatments to combat immune disorders using its Antibody-Catch™ technology platform. The company currently employs 15 people and has raised a significant amount in equity funding from top-tier venture capital funds. The first dysimmune neuropathy program recently entered the clinical development phase and further programs are planned to follow. To support our team, we currently have an open position as:

Global Head of Regulatory Affairs

You will have a minimum of 10-15 years' experience in a senior Regulatory Affairs leadership position in a Pharmaceutical/Biotech Company, preferably in the area of complex molecules and/or biologics. Experience with both FDA and EMA interactions is required and experience in rare diseases and dealing with other regulatory bodies, for example in Asia, is very desirable. The candidate should have experience in supporting the full spectrum of drug development (pre-clinical, clinical and CMC), be able to outline a regulatory strategy for the technology platform and have a desire to work balancing both a strategic and hands-on approach in an exciting start-up. Ideally, you have an MSc or PhD in Life Sciences.

Responsibilities:

- Responsible with senior management team for development and implementation of innovative regulatory strategies and execution plans to accelerate access to market
- Serves as a strategic & functional partner with third parties (RA), management and cross-functional team members to define the development and regulatory strategy
    - Responsible for vendor oversight for all regulatory affairs related activities including budget
    - Addresses ad-hoc regulatory issues with 3rd parties, proposes responses and execute plans
    - Responsible for the regulatory compliance
- Oversight of the day-to-day operations and of the planning, preparation, review and evaluation of documents for submission to health agencies
- Provides guidance on regulatory agency expectations and timelines to facilitate management decision-making and launch planning
- Maintains current knowledge of regulations and other issues that affect products and industry. Disseminates and discuss with key staff, as appropriate, and in a timely manner
- Supports QA and CMO during sponsor and RA audits
- Maintains positive relationships with health agencies on submissions, communications, scientific advice and specific projects. Represent Regulatory Affairs at FDA/EMA/ Pre-Approval Inspections. Interact with outside legal counsel and consultants, as needed, on regulatory issues
- Ensures process and resources are in place to allow timely review of internal documentation such as change control information, method transfer packages, batch records documentation, validation protocols, and reports

Qualifications:

- At least 10-15 years' leadership experience in Regulatory Affairs in large and/or small Pharmaceutical / biotech companies
- Extensive working knowledge of the drug development and submission process
- RA Management experience across multiple projects with FDA and EMA and, ideally, other regulatory bodies e.g. in Asia
- Experience managing Clinical Trial applications & Phase transitions in early stage development with FDA and EMA, FDA meetings, EMA Scientific advice etc.
- Experience in supporting the full spectrum of drug development, with specific experience in CMC
- Excellent knowledge of Regulatory Affairs, international regulations, guidelines and best practices
- Experience with Rare Diseases is a significant plus
- Strong leader with experience in implementing and shaping the company's RA processes and strategies with the ability to be "hands on" as needed
- Strong communication skills with all the key stakeholders to ensure RA vision and strategy is understood and implemented correctly internally and externally
- Proactive, strong minded, quick thinker and assertive
- Able to motivate a cross-functional matrix team, and bring out the best out of each individual
- Practical and pragmatic; and able to rapidly integrate into a small team

Working place is Basel. We offer a competitive remuneration package. If you meet the requirements for this exciting position and wish to play a key role in the development of novel therapeutics which we believe will transform the treatment of autoimmune diseases, please contact us, we are looking forward to meeting you!

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