Numab Therapeutics AG is an expanding, clinical stage Swiss biotech company based in Horgen, canton of Zürich. The company is focused on the discovery and development of novel, antibody fragment-based therapeutics. With our breakthrough antibody-discovery and multi-specifics engineering platform, we are committed to the development of differentiated therapeutics with a focus on helping oncology patients in need.

To expand and develop Numab's proprietary immune-oncology and autoimmune disease therapeutics pipeline we are looking for a highly motivated and experienced professional to manage and provide leadership for regulatory agency interactions and submissions as our

Head of Regulatory Affairs (80 - 100%)

The Head of Regulatory Affairs will support the organization with the development of global and regional regulatory strategies, informed by robust regulatory intelligence, for our therapeutic areas of focus. Importantly, successful candidates will possess significant, relevant experience in regulatory affairs and compliance, as well as excellent writing and presentation skills, be detailed-oriented and possess the ability to carry out multiple tasks while maintaining a high level of quality.

This role will report to the Chief Medical Officer. The ideal candidate will thrive in an energetic, fast-paced environment, working with highly motivated and passionate people. Applicants must have also demonstrated strong interpersonal and verbal communication skills.

Your Responsibilities

To perform this job successfully an individual must be able to perform each essential function effectively:

- Oversee preparation and filing of all regulatory documents globally, in collaboration with Numab's contracted regulatory consultants and CROs; provide primary authoring and hands-on support as needed, prior success working with cross-functional teams and/or mentoring junior staff in regulatory affairs
- Serve as primary regulatory strategic advisor for the product development team(s), providing actionable regulatory input to Numab's development programs
- Maintain regulatory dossiers, including provision of support to CMC and Quality Heads for manufacturing dossiers and related documentation, to ensure continued compliance with applicable laws and regulations
- Develop trusted relationships with key regulatory authorities; facilitate meaningful health authority interactions to achieve optimal outcomes in line with Numab corporate objectives and timelines.
- Identify and create opportunities for innovative product claims and product positioning to support development of the business strategy; evaluate options to accelerate development from a regulatory perspective
- Lead the development and execution a global regulatory intelligence strategy; assess precedent, regulatory intelligence, and competitive environment from a regulatory perspective and generate impactful summaries and strategic advice for Numab management regarding regulatory initiatives for the organization and its assets
- Proactively maintain knowledge of the regulatory environment impacting the company, including emerging industry trends and changing regulatory expectations and mitigate regulatory risks impacting development programs

- Provide training and interpretation of FDA, EMA, and other regulatory requirements to company personnel

Your Skills and Professional Experience

- BS/BA (or equivalent) in chemical/biological sciences or pharmacy; candidates with advanced degree (e.g., PhD, JD, MD, and/or PharmD) and regulatory affairs degree or RAC Certification/equivalent preferred
- 10+ years' experience in pharmaceutical/biotechnology industry and/or within a regulatory agency, with at least 5 years of direct regulatory experience, ideally in a leadership role.
- Thorough understanding of regulations and guidance governing biologics in all phases of development, with extensive working knowledge of the US, European, and Asian regulations for biologic products and command of ICH GxPs
- Substantial experience in all aspects of regulatory affairs, with a successful track record of preparing INDs, NDAs/BLAs, MAAs, CTAs, IMPDs, safety reports, annual updates, and other documents for submission to relevant regulatory authorities
- In-depth understanding Orphan Drug, Breakthrough Therapy, and Fast-Track Designations, the Accelerated Approval Program, and development of PIP/iPSPs
- Experience with regulatory aspects of drug-device combination development and/or companion diagnostics (CDx)
- Capable and competent in setting strategies as well as taking a hands-on approach to all regulatory activities, while simultaneously building the department to ensure successful scalability as Numab's pipeline grows
- Understands and interprets complex scientific issues across projects and therapy area(s) as it relates to regulatory requirements, regulatory intelligence, policy, and strategy for applicable development regions
- Demonstrated ability to balance multiple projects to achieve goals and meet deadlines and company expectations with a high level of quality
- Advanced user of MSOffice Suite (e.g., Word, Excel, Project, PowerPoint, Outlook)
- Willingness to travel, both domestic and internationally, approximately 10% for meetings as required

What we Offer:

- A diverse field of activity in a dynamic SME with an inspiring, entrepreneurial atmosphere
- Flat structures and fast decision-making
- The opportunity to take responsibility, help shaping and implementing solutions
- Flexibility to work remotely
- Employment conditions in line with the market, superior pension plan and opportunities for further personal development
- Regular bonus and participation in the employee stock option plan
- Participation in several fun team events
- A workplace near the city of Zurich overseeing the lake

We are looking forward to receiving your full application with reference number NB0104 to hr@numab.com.