Santhera Pharmaceuticals is a Swiss specialty pharmaceutical company focused on medical science and the development and commercialization of innovative pharmaceutical products for the treatment of rare neuromuscular diseases with high unmet medical need. For further information, please visit the Company's website www.santhera.com

Come and join our team to contribute to providing treatment options for patients with rare diseases that have a severe impact on the lives of affected children and adults. You can make a difference as:

Senior Manager, Drug Regulatory Affairs 80-100%

Location: Pratteln, Switzerland (50% Hybrid)

Scope of Work

The Senior Manager, Drug Regulatory Affairs, is responsible for leading a range of global regulatory activities, encompassing both strategic and operational responsibilities across drug development, registration, and post-marketing phases. This role offers the opportunity to work in close collaboration with key cross-functional teams — including Clinical Operations, Clinical Sciences, Pharmacovigilance, Biostatistics, Preclinical and CMC, as well as Marketing and Commercial.

Please note: We are considering both Manager and Senior Manager levels for this position, depending on the candidate's experience.

Key Responsibilities

- **Anticipating, planning and driving post-approval procedures:** Preparation of regulatory documents, ensuring quality and accuracy, coordinating cross-functional input, and leading submissions, including variations/extensions, PAMs, renewals, scientific advice and meetings with health authorities, and acting as the main HA regulatory contact point.
- **Global expansion of Agamree**: Serving as contact point for local partners and representing DRA in operational tasks for new markets; providing regulatory support for filings in RoW countries; managing post-approval activities in collaboration with local partners.
- **Regulatory Intelligence**: Identifying and monitoring relevant guidance, regulations, and sources to ensure ongoing regulatory compliance.
- **Providing cross-functional support as required**: Supporting Safety and Pharmacovigilance (PSURs, DSURs, PASS, RMP, etc.), Clinical Science/Operations, Quality Assurance, Supply Chain, and Commercial (review of promotional/non-promotional materials, market launch), and participating in due diligence activities.
- **Critical review of documents**: Ensuring accuracy, scientific validity, and optimal presentation of key documents such as IBs, protocols, and IMPDs.
- **Document management**: Filing and archiving regulatory documents per SOPs and maintaining electronic filing systems and internal regulatory archives.
- **Clinical Trial Authorisation applications and maintenance**: Preparing and submitting clinical trial applications and amendments, managing trial notifications, contributing to clinical trial strategy decisions, supervising regulatory CRO counterparts, liaising with regulatory authorities, supporting the Study Management Team with regulatory guidance, and assisting DS&PV with DSUR preparation and submission.

Required Qualifications & Experience

- A minimum of 5–8 years of experience in Drug Regulatory Affairs in a pharmaceutical company or contract research organization (CRO)
- A minimum of a master's degree in life sciences
- Knowledge of CH, EU and international regulations
- Previous experience in operating within complex matrix organizations
- Fluency in English, both written and oral
- Knowledge of German and other languages would be an asset

Required Competencies & Skills

- Excellent communication, interpersonal and networking skills
- Self-motivation, personal resilience, perseverance, energy and drive
- Ability to work independently and collaboratively, as required, in a matrix organization
- Excellent planning and organizing skills
- Flexibility in adapting to changing priorities and deadlines
- Capable of dealing with ambiguity, risk taking and decision making in a fast-paced entrepreneurial environment
- Open minded, solution oriented

For this position, the relevant working/residency permit or Swiss/EU-Citizenship is required.

If you are interested in a multicultural, challenging, and innovative working environment and your profile matches our requirements, we are looking forward to receiving your online application in English via LinkedIn or Email, at career@santhera.com

Note for agencies: Recruitment agencies are kindly invited to refrain from sending unsolicited CVs to Santhera.