Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular and pulmonary diseases with high unmet medical need.

Santhera has an exclusive license for all indications worldwide to vamorolone, a first-in-class dissociative steroid with novel mode of action, currently investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. The clinical stage pipeline also includes lonodelestat (POL6014) to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases as well as an exploratory gene therapy approach targeting congenital muscular dystrophies. Santhera out-licensed ex-North American rights to its first approved product, Raxone® (idebenone), for the treatment of Leber's hereditary optic neuropathy (LHON) to Chiesi Group.

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 Technical Regulatory Affairs (CMC)

at our Headquarters in Pratteln, Switzerland (close to Basel) on a full-time basis (100%).

Scope of Work

The role reports to the Head GMP Quality Management and will collaborate closely with other functions such as Technical Development, Supply Chain Management and Regulatory Affairs across geographical boundaries when preparing for filing of a new product first in the US and later in Europe. Externally, in the newly created position, the job holder will collaborate with Health Authorities, contract manufacturers and other partners.

The core responsibilities are:

- Preparing, overseeing and advising global CMC and Quality related strategies to ensure acceptance, rapid review and approval of marketing applications, supplements/variations and other submissions which present CMC information
- Compliant and optimized preparation and update of the CMC dossier sections of assigned products especially with a focus on US and EU
- Development of CMC strategies for new marketing applications and post-approval CMC activities
- Identifying supportive documents required for global submissions and negotiating the delivery of approved technical source documents in accordance with project timelines
- Ensuring that the global regulatory CMC strategies for assigned products are consistent with team and business goals, missions and objectives and meet Health Authority requirements
- Ensuring effective communication of CMC regulatory strategy, risks, and overall plans to leadership and teams
- Supporting all regulatory activities to provide high quality CMC sections of regulatory documentation
- Overseeing all CMC regulatory aspects for pharmaceutical products, from development to registration and life cycle at global level
- Support QA operational activities (e.g. change controls, deviations, complaints)
- Support in preparation of Health Authority inspections

Required background and experience:

- Minimum Bachelor degree in a scientific discipline (e.g. pharmacy, chemistry, engineering, life science) or similar education
- At least 10 years relevant experience in the pharmaceutical / biotech industry
- At least 5+ years of experience in Regulatory CMC (preparation, writing, and functional review of global CMC documents for regulatory submissions including variations/supplements as well as registration submission at least in US/EU (any other region is a plus))
- Broad background of registration experience gained from working in the pharmaceutical / biotech industry or a regulatory authority in one or more of the ICH regions
- Professional experience in pharmaceutical manufacturing, analytical development, and quality assurance/control or related technical field is a plus
- Proven track record in writing CMC part of the dossiers with focus on US/EU
- Strong knowledge of global guidance, regulations and ICH/GMP requirements related to CMC topics
- Knowledge of and broad experience with regulatory procedures and legislation for drug development, product registration and license maintenance in the US/EU
- Experience in gap and risk analysis of CMC part
- Experience in direct communication and negotiation with regulatory bodies on CMC topics
- Experience and knowledge in the preparation of major regulatory submissions and supportive amendments or supplements
- Fluency in English (German or any other language is a plus)

Required competencies and skills:

- Good understanding of scientific, technical, quality, regulatory in the pharmaceutical industry
- Ability to work with tight deadlines as well as strong planning, organizing and time management skills
- Strong verbal and written communication skills
- Ability to work independently to manage multiple projects in a fast-paced environment
- Strong problem solving and analytical skills
- Ability to identify opportunities / major issues and to communicate impact
- Reliable team-player

If you are attracted by this exciting opportunity and the prospects of joining a motivated international team operating on a global level, please send your CV and motivation letter mentioning the position "**Senior Manager Technical Regulatory Affairs (CMC)"** as the subject by email to: career@santhera.com

Strictly no agencies

Recruitment agencies are kindly requested to refrain from sending unsolicited CVs to Santhera.