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 Technical Regulatory Affairs (CMC) (100%)
Location: HQ Pratteln (CH), Hybrid

Who you are

As part of Santhera's growth and further expansion of our team, we are looking for an enthusiastic and experienced professional who is willing to work across boundaries and wants to shape the future.

Scope of Work

The Senior Manager Technical Regulatory Affairs (CMC) is responsible for all activities in the field of CMC regulatory affairs within Technical Development & Operations (TDO) for Santhera's development and commercial stage projects.

The role reports to the Chief Technology Officer and will collaborate closely with internal functions such as Technical Development, Clinical and Commercial Supply Chain, Quality Assurance and Drug Regulatory Affairs. Externally, the job holder will collaborate with Health Authorities, contractors and Santhera's partners across geographic boundaries.

Key Responsibilities:

- Oversee CMC regulatory aspects for company's projects from development to registration and during life cycle.
- Define CMC submission strategy, planning and content together with internal functions and in alignment with regulations, guidelines, policies and procedures.
- Manage the preparation and functional review of CMC documents for regulatory submissions including variations/supplements worldwide.
- Author and provide CMC input to relevant documents required for global clinical (IND/IMPD) and commercial (NDA/MAA) submissions for drug substances (small molecules) and drug products.
- Compile variation packages and annual reports.
- Prepare and review responses to agency questions and prepare briefing documents for advice meetings.
- Version tracking of quality modules setup and maintain necessary CMC regulatory processes and systems.
- Support cross-functional CMC Team meetings as member and subject matter expert.
- Ensure effective communication of CMC regulatory strategy, risks, and overall plans to CMC teams and DRA.
- Provide regulatory advice and strategic input to internal and external customers.

- Perform regulatory assessments for CMC deviations and change controls.
- Support improvement initiatives regarding technical regulatory and GMP processes and tools.
- Conduct technical regulatory intelligence on emerging health authority guidance and current thinking.
- Maintain transparency of information across functions.

Required Background and Experience:

- Minimum bachelor's degree in a scientific discipline (e.g. pharmacy, chemistry, engineering, life science) or similar education.
- At least 5 years of experience in Technical Regulatory Affairs involving preparation and authoring of CMC sections for international regulatory documents, submission variations and administration through product life cycle.
- Strong understanding of technical regulatory requirements for new drugs products and new drug substances.
- Sound operational experience in Technical Regulatory Affairs and good technical understanding of the pharmaceutical/scientific environment.

Required Competencies:

- Strong understanding of scientific, technical, quality, regulatory in the pharmaceutical industry across the product life cycle.
- Ability to work according to deadlines as well as strong planning, organizing and time management skills.
- Good organizational and communication skills, both written and oral skills, and "do-what-it-takes" attitude.
- Fluency in English (verbal and written), other languages are advantageous.
- Independently motivated, detail-oriented and good problem-solving ability.
- Eager to learn and grow, and sufficient to multi-task in a fast-paced environment.
- Reliable team player.

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

If you are interested in this exciting opportunity and the prospects of joining a motivated international team operating on a global level, we are looking forward to receiving your online application in English with the subject "Senior Manager Technical Regulatory Affairs (CMC)" at career@santhera.com.

Strictly no agencies: Recruitment agencies are kindly invited to refrain from sending unsolicited CVs to Santhera.