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, which was investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. The Company is planning for filing for approval with the US FDA in Q1-2022. The clinical stage pipeline also includes lonodelestat to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases. Santhera out-licensed rights to its first approved product, Raxone® (idebenone), outside North America and France 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

Technical Development Manager

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

Scope of work

The **Technical Development Manager** is responsible for activities in the field of Technical Development & Operations (TDO), in particular for defined technical development projects.

The role reports to the Senior Technical Development Manager.

The core responsibilities are:

- Support technical development projects including:
  - Pharmaceutical and chemical development
  - Manufacturing
  - Analytical development
  - Technical regulatory
  - GMP compliance aspects
  - Vendor evaluation and selection
  - Packaging and shipping
  - Life cycle and IP proposals
- Representation of the TDO organization internally and externally for defined development programs
- Develop strategies for technical development and manufacturing for Santhera compounds / programs
- Evaluate, select/qualify and maintain vendors and service providers in the field of technical development, manufacturing and other services
- Negotiate, approve and maintain relevant contracts with vendors and service providers, such as development and supply agreements, GMP agreements
- Closely collaborate with other TDO functions (technical regulatory, QA/GMP compliance, clinical supply, commercial supply chain and distribution)

- Closely collaborate with vendors on assigned TDO projects and drive, oversee and control their activities. Involve other TDO functions as required
- Plan and perform due diligence activities related to CMC/quality aspects of potential in-licensing candidates
- Evaluate and propose life-cycle opportunities for Santhera products and development candidates from a TDO perspective
- Identify and propose opportunities to establish additional new IP or improve existing IP positions for development and established projects
- Provide technical development expertise into the organization and thoroughly plan, develop, execute and implement suitable technical and operational solutions addressing development challenges
- Support CMC/quality related interactions with regulatory authorities and provide input / write / review regulatory documents in close collaboration with TRA.
- Estimate / calculate cost of goods at different stages of development
- Maintain state-of-the-art knowledge including latest developments and technical expertise for relevant production technologies for API, drug product and packaging
- The job holder has the responsibility to train and comply with the SOPs indicated in the SOP training matrix

Required background and experience:

- PhD in pharmacy, chemistry or equivalent
- 5+ years in the pharmaceutical industry
- 3+ years in iechnical development
- 2+ years in chemical/pharmaceutical/analytical development
- Experience in medical devices is a plus

Required competencies:

- High level of understanding in EU /US technical regulatory requirements and in an GMP environment
- Good understanding of scientific, technical, quality, regulatory and commercial aspects in the pharmaceutical industry
- Capability to balance between high-level strategic perspective and proper attention to detail when a hands-on approach is required
- Flexibility to adapt to changing priorities and deadlines
- Ability to work independently and collaboratively, as required, in a matrix environment
- Team player, collaborative attitude able to make a positive impact in the team
- Problem solving, project and risk management skills
- High level of English language proficiency, German language appreciated
- Used to work in an international environment
- Intercultural communication and behavior skills

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 "**Technical Development Manager"** as the subject by email to: career@santhera.com

Strictly no agencies

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