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 is building a Duchenne muscular dystrophy (DMD) product portfolio to treat patients irrespective of causative mutations, disease stage or age. A marketing authorization application for Puldysa® (idebenone) is currently under review by the European Medicines Agency. Santhera has an option to license vamorolone, a first-in-class dissociative steroid currently investigated in a pivotal study in patients with DMD to replace standard corticosteroids. The clinical stage pipeline also includes POL6014 to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases, as well as omigapil and 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 more information about Santhera, please visit the company's website www.santhera.com

We are currently looking to hire a:

Technical Development & Operations Manager

To be based in our HQ office in Pratteln, Switzerland.

Scope of Work

The role reports to the Senior Technical Development & Operations Manager, based in Pratteln, and works in close collaboration with other internal departments (e.g. Quality Assurance, Supply Chain, Clinical Supply, Regulatory Affairs, etc) and other external TDO partners.
The overall scope of the role is to take over responsibilities in the field of Technical Development & Operations in particular for defined Technical Development projects.

The responsibilities for this role include the following:

- 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 organisation 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.

Required background and experience:

- PhD in Pharmacy, Chemistry or equivalent
- Minimum 5 years of experience in the Pharmaceutical industry
- Minimum 3 years of experience in Technical Development, ideally in more than 1 field
- 2+ years in Pharmaceutical/Formulation/Analytical Development
- Experience in Medical Devices is a plus
- 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
- Experience in Gene Therapy manufacturing / analytics is a plus
- High level of English language proficiency, German language appreciated

Required competencies and skills:

- Excellent communication and interpersonal skills
- 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
- Used to work in an international environment
- Intercultural communication and behavior skills
- Self-motivation, proactive attitude, solution oriented
- Personal resilience, perseverance, energy and drive

If you are interested to apply for this role, please send your application by email at career@santhera.com

Strictly no agencies

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