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.

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 Project Leader Drug Product
Starting date: immediately
Location: HQ Pratteln (CH), hybrid

Who you are

You are organized, flexible, hands-on, and most importantly willing to learn and develop your professional expertise. You are experienced in matrix leadership and can provide an expert content and strategic guidance for diverse development and commercial stage projects.

Scope of Work

The Technical Project Leader Drug Product is responsible for leading all activities in the field of development projects within Technical Development & Operations (TDO) for Santhera`s development and commercial stage projects. In this role, you'll be managing multiple consulting projects of varying complexity and ensuring on-time and on-budget delivery for high client satisfaction. We need insightful, detail-oriented people who take pride in their work and their relationships, so we can all work together to make a difference in rare disease area.

The role reports to the Head Technical Development & Operations (TDO) and will collaborate closely with internal functions such as Technical Development, Clinical and Commercial Supply Chain, Quality Assurance and Regulatory Affairs. Externally, the job holder will collaborate with Health Authorities, contractors and Santhera`s partners across geographic boundaries. The job holder has the responsibility to train and comply with the Quality Documents indicated in the Santhera Training Matrix.

The core responsibilities are:

- Lead Technical Development projects including:
    - Pharmaceutical development of drug products
    - Clinical and commercial manufacturing
    - Technology transfer
    - Analytical development
    - Technical Regulatory
    - GMP compliance aspects
    - Outsouring including vendor evaluation and selection
    - Packaging and shipping
    - Life cycle and IP proposals
    - Project planning (strategy, timeline, budget, cost tracking, resource allocation, activities)

- Representation of the TDO organization internally and externally for assigned development programs
- Develop strategies and execute for technical development and manufacturing for Santhera compounds/ programs including contingency planning and risk assessments as appropriate
- 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.
- Resource and budget planning for development. Estimate / calculate cost of goods at different stages of development. Establish TDO specific sub-plans per project within the global planning tool in close collaboration with respective Project Planning Manager.
- Maintain state-of-the-art knowledge including latest developments and technical expertise for relevant production technologies with a general focus on Drug Product and Packaging. Contribute to knowledge creation and sharing within the organization.
- Support supplier audits by GMP QA as technical expert.

Required background and experience:

- Master´s Degree in Pharmacy, Chemistry or equivalent
- 5+ years in the Pharmaceutical Industry
- 5+ years in Pharmaceutical development/Formulation/Analytical Development
- 2+ years experience in leading matrix teams
- 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 desirable
- Used to work in an international environment
- Intercultural communication and behaviour skills
- Presentation skills and scientific/technical writing 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 Project Leader Drug Product"** 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.