



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 plans to complete the ongoing rolling submission of its filing for approval for vamorolone with the US FDA in Q2-2022. 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:

Outsourcing and Contract Manager

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

Scope of Work

The Outsourcing and Contract Manager is responsible for seeking/identifying potential External Service Providers (ESP), evaluating, selecting, negotiating and contracting across Santhera Development functions (Drug Safety & PV, Drug Regulatory Affairs, Quality Management, Clinical Operations, Clinical Science, Biostatistics, Non-clinical). The role will include oversight and follow-up of ESPs performance through KPIs to ensure that outsourcing activities are conducted in adherence to contracts and applicable compliance standards and guidelines. In cases of non-adherence by ESPs, the incumbent will take an active role in problem solving, while working with the function, in finding mutual resolution.

The position includes the management of consultancy agreements across the Development area.

The Outsourcing & Contract Manager works closely with study and program management teams, Quality Management, Legal counsel, Finance and reports to the Head of Development.

The core responsibilities are:

- Identify and evaluate potential ESPs.
- Partner with Development function lead, Clinical Trial Leaders and other study management and program team member(s) as needed to assess outsourcing needs and requirements within timelines. Assist in the definition of work specifications and establish the Request For Information (RFI) and Request For Proposal (RFP) once Confidentiality Agreements from concerned parties are obtained.
- Facilitate ESP selection and ensure documentation of rationale for selected vendor (SWOT analysis) using a risk-based vendors selection process (e.g. structured questionnaires based on quantitative, qualitative and performance criteria).
- Support the development, negotiation and timely execution of ESP contracts ensuring quality as per defined specifications and oversee legal & financial review.

- Facilitate implementation of quality agreement between Sponsor and ESPs.
- Negotiate contract terms, including pricing, deliverables, milestones and payment schedule, ensuring that the agreements with the ESPs are in line with Santhera forecasts.
- Support the Development function lead(s), Global Program Lead and Clinical Trial Leader(s)/Manager(s) (CTL/CTM), as applicable, to define key risk indicators (KRIs) and Key Performance Indicators (KPIs) measuring performance as well as risks associated with quality standards and contract's deliverables in all operational areas (systems, processes and infrastructure).
- Monitor ESP performance as per defined timeframe in adherence to contractual terms and according to defined Key Performance Indicators and Key Risks Indicators.
- Ensure ESPs qualification assessment/audits liaising with Quality Management and support due diligence activities as required.
- Support the review of key ESP SOPs and alignment with Santhera requirements and standards.
- Continuously monitor the outsourcing environment to keep current with ESPs, industry outsourcing trends, KPIs, KRIs and performance benchmarks.
- Determine with Development function lead(s), Global Program Lead(s), CTL/CTM and Head GCP and Head Quality Management, vendor audits to be required.

Required competencies:

- Leadership ability as characterized by motivation to deliver quality results under tight timelines and budget
- Excellent planning and organisational skills, ability to manage multiple programs and processes simultaneously while demonstrating the ability to prioritize &/or re-prioritize as the landscape changes
- Excellent communication and presentation skills, both written and verbal
- Excellent interpersonal, negotiation and influencing mindset and skillset
- Pro-active and problem-solving attitude
- Self-motivation, able to work independently as well as participating in cross-functional teams
- Personal resilience, perseverance, energy and drive
- Team player, collaborative attitude

Required background and experience:

- University or equivalent education/degree
- Mandatory 5 years of experience in clinical research with a Contract Research Organization (CRO) or pharmaceutical company
- Minimum 2 years of previous experience in managing clinical outsourcing and/or External Service Provider (ESP) and/or Functional Service Provider (FSP)
- Advanced understanding of the clinical development process and understanding of the management of clinical trials, GCP, GVP, GMP Quality functions, pre-clinical, Drug Safety
- Prior experience in working in global cross-functional (matrix) and multicultural teams
- Experience with interacting effectively with internal and external customers and groups

- Conflict management experience with ability to reach mutual efficient issue resolution
- Familiarity with Outsourcing industry, i.e. CRO, Central Laboratories/Reference Laboratories, ECG, IVRS; external auditing services, etc.

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 “**Outsourcing and Contract Manager**” as the subject by email to: career@santhera.com.

Santhera Pharmaceuticals is committed to creating a diverse workforce and providing equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, sex, sexual orientation, gender identity, gender expression, parental status, national origin, age, disability, citizenship status, genetic information or characteristics, marital status, status as a Vietnam era veteran, special disabled veteran, or other protected veteran in accordance with applicable federal, state and local laws, and any other characteristic protected by law.

Strictly no agencies

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