Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative pharmaceutical products for the treatment of orphan mitochondrial and neuromuscular diseases.

In September 2015, our leading product Raxone® (idebenone) received European Marketing Authorization in the treatment of patients with LHON (Leber's Hereditary Optic Neuropathy). Raxone® is not only the first and only medicine approved for this condition, but it is also the first medicine approved for any mitochondrial disorder.
The company currently develops Raxone® in other areas of high unmet medical needs, like the treatment of Duchenne Muscular Dystrophy (DMD) and Primary Progressive Multiple Sclerosis (PPMS). In addition, Santhera's pipeline includes omigapil, an investigational drug with anti-apoptotic properties, a compound in development to address unmet medical needs for patients with Congenital Muscular Dystrophy (CMD).

For more information, please visit the company's website www.santhera.com

We are currently looking to hire a:

Senior Clinical Supply Manager

to be based at our Headquarters in Liestal, close to Basel.

Scope of Work

This role reports to the Head of Supply Chain Management & Distribution within the Technical Development & Operations (TDO) organization and is responsible for ensuring timely availability of Investigational Medicinal Products ("IMP") at clinical trial sites in compliance with study protocols, Santhera's SOPs and applicable regulations including GMP/GDP and GCP. This implies the planning, contracting, surveilling and supporting of both manufacturing including labelling, as well as distribution services. To be successful in this role effective interaction with a number of internal functions and the Study Management Teams in particular, as well as with third party Contract Research Organizations ("CRO") is crucial.

The responsibilities for this role include the following:

- Representation of the Clinical Supply function ("TDO") in Study Management Teams ("SMT")
- Development of the supply plan and distribution setup for new clinical trials, based on the trial protocol and in collaboration with the SMT
- Specification of IMPs for new studies including lead of label generation
- Requests for quote and contracting of manufacturing and distribution services, in close collaboration with the head of Technical Development & Operations, the GMP Compliance Officer and the SMT leaders
- Vendor selection, contracting and relationship management for providers of IMP manufacturing and distribution related services
- Management of IMP packaging activities: Planning, order management, drug product supply and labelling instructions, documentation
- Management of label related activities: Generation of master labels, manage translations, review and approval of label proofs
- Materials and inventory management of clinical trial material, components and comparators: Requirements planning, inventory control, supply planning
- Batch tracking for IMPs and clinical drug product
- Manage IMP distribution activities: Determination and implementation of appropriate methods of IMP stock control; operational surveillance of IMP stocks and timely replenishment
- Filing of relevant documentation in TDO files and Trial Master File ("TMF")
- Support audits at IMP manufacturers and distribution service providers

- Setup and maintenance of IMP related SOP's
- Manage finance activities: Planning and budgeting for IMP manufacture & distribution
- Contribution to clinical drug product master data management

Required background and experience:

- Mandatory academic training, preferably in a life science subject;
- English language proficiency level oral and written
- 5+ years of experience in Clinical Supply and Distribution Management functions in the pharmaceutical industry
- In-depth understanding of pharmaceutical manufacturing and distribution processes for clinical trials and capability of applying such understanding to different clinical trial types and settings
- Proven experience in independent end-to-end responsible performance of all operational activities required to ensure timely supply of IMP stocks to study centres worldwide
- Knowledge of materials management techniques
- Ability to set up viable supply and distribution plans and concepts from the study protocols and from SMT information
- Experience in multi-country label generation for open label and blinded trials
- Experience in distribution setup and control techniques, including Interactive Response Technology)
- Knowledge of quality (GMP, GDP, GCP) and regulatory requirements and principles and understanding of their impact on manufacturing / packaging, storage, as well as distribution of IMP

Required competencies and skills:

- Effective collaboration with clinical study teams and other functional representatives, as well as with the third party manufacturing and distribution service providers
- Proactive work style and ability to gauge the impact of protocol changes or of deviations of trial performance from performance plans on IMP supply and distribution
- Efficient performance of operational activities, with a dedication to detail and accuracy
- Sense of urgency and service-mindedness
- Flexibility to accommodate business needs as and when they occur

If you are interested to apply for this role, please send your CV and motivation letter by email to:
career@santhera.com

Strictly no agencies

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