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:

GCP/GVP Quality Manager

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

Scope of Work

The **GCP/GVP Quality Manager** will provide GCP/GVP Auditing and Quality Management support to Santhera's clinical development program and marketed products to ensure Santhera's clinical development and drug safety/pharmacovigilance activities are conducted in compliance with applicable regulations.

The core responsibilities are:

- Ensure timely planning and execution of risk-based GCP/GVP audit programs (internal/external)
- Conduct and/or manage GCP and GVP audits, including but not limited to, internal processes, external vendors and clinical investigator sites; determining compliance status and identify compliance risks
- Conduct internal and external GCP/GVP audits
- Support GCP/GVP inspection readiness activities and GCP/GVP inspections
- Establish effective means for communicating audit and inspection outcomes, developing metrics, measuring trends and driving improvements
- Monitor and reinforce timely completion of corrective and preventive actions that are defined to address GCP/GVP issues, regardless of the source
- Support and contribute to the establishment and revision of GCP/GVP quality documents

Required background and experience:

- Minimum: Bachelor's Degree in Science Life Science or a related discipline and/or allied medical field (e.g. nursing, Pharmacy)
- Minimum 5-7 years' experience in the pharmaceutical/life science industry
- Current and thorough knowledge of US FDA, EU and ICH regulatory requirements and guidelines applicable to clinical research/development and Pharmacovigilance Legislation
- Extensive experience in and knowledge of internal and external GCP/GVP auditing and quality systems operations.
- Experience with GCP/GVP Health authority inspections and inspection readiness activities

- Excellent communication and interpersonal skills, including the ability to liaise successfully with project teams, investigators and clients
- Travel requirement up to 30%

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 "**GCP/GVP Quality 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.