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:

Clinical Trial Documentation Specialist

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

Scope of Work

The role reports to Head of Clinical Operations and ensures Trial Master Files (TMF)/ electronic Trial Master Files (eTMF), across studies and different management models (outsourced to External Service Provider (ESP) or maintained internally), are accurately set-up, maintained and archived, in collaboration with responsible Clinical Trial Leader/ Clinical Trial Manager (CTL/ CTM) and manages TMFs/e-TMFs quality checks in order to ensure audit/inspection readiness.

The responsibilities for this role include the following:

- Review and approve TMFs Table of Contents (ToC) according to internal requirements, in collaboration with responsible CTL/CTM
- Review ESP TMF-related SOP(s) in comparison with Santhera SOP, provide feedback on possible gaps & inconsistencies and suggest ways to manage them to CTL/CTM, in view of developing study specific TMF filing process
- Develop TMF oversight plan to be reviewed by CTL/CTM and approved by the relevant team members
- Implement/streamline TMF filing process & documents flow for studies where TMF/ eTMF is partially or fully outsourced
- Perform TMF/eTMF quality checks including remote & at ESP premises, as applicable
- Track and review TMF/ eTMF documents for completeness, accuracy, and quality within required timelines while maintaining consistency and attention to details
- Upon identification of TMF quality issues or missing documentation, propose resolution plan (including responsibility and timelines) to CTL/CTM, implement plan accordingly and follow up issues until resolution
- Assemble or supervise assembly of TMFs, including combination of in-house files with CRO-derived components, in collaboration with CTL/CTM and Study Management Team (SMT)
- Perform/oversee overall studies TMFs implementation & filing status within required timelines and report on advancement and status on an ongoing basis to CTL/CTM
- Attend regular SMT meetings, provide update on TMF general status and discuss possible pending actions

- Ensure TMF/eTMF is audit/inspection ready, alert CTL/CTM in case of issues and propose resolution plan
- Implement best practices and lessons learned, and share outcome with the Clinical Operations Team
- Perform TMF pre-audit and CAPA resolution activities ensuring satisfactory outcome within agreed timelines
- Adhere to personal development plan and maintain training records to ensure appropriate level of competence in compliance with this job description including GCP, etc
- Other duties, activities and projects as assigned

Required background and experience:

- University or equivalent education/degree
- Mandatory 3-5 years of experience in clinical development and/or clinical operations within a pharmaceutical company or CRO
- Minimum 3 years' experience of clinical trial documentation, working with TMF and electronic filing systems (eTMF experience is advantageous)
- Strong knowledge of International Conference on Harmonization (ICH)/Good Clinical Practice (GCP) guidelines
- Experience with e-TMF tools would be a plus
- Strong computer skills, including working with the Microsoft suite of programs
- Prior experience in working in global cross-functional (matrix) and multicultural teams
- Fluency in English, both written and oral

Required competencies and skills:

- Excellent communication, interpersonal and networking skills
- Pro-active and problem-solving attitude, strong organizational skills
- Self-motivation, able to work independently as well as on cross-functional teams
- Excellent planning and organizing skills, able to prioritize workload to ensure departmental needs and timelines are met
- Personal resilience, perseverance, energy and drive
- Team player, collaborative attitude

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.