Santhera Pharmaceuticals is a Swiss specialty pharmaceutical company focused on medical science and the development and commercialization of innovative pharmaceutical products for the treatment of rare neuromuscular 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:

Drug Safety Operations Lead

Location: Pratteln, Switzerland (Hybrid)

Scope of Work

The Drug Safety Operations Lead reports to the Global Head of Drug Safety & Pharmacovigilance (GH DS&PV) and supports the GH DS&PV and the European Qualified Person for Pharmacovigilance (EU QPPV) on Drug Safety & Pharmacovigilance activities, for all Santhera products under development and on the market.

The overall scope of the role includes the organisation of and participation in:

- oversight of PV system operation and compliance across the entire lifecycle of the products
- oversight and management of the main PV service vendors
- oversight and maintenance of safety systems validation
- safety data management, reporting and data presentation, compliance metrics
- development and maintenance of a wide range of safety related documents (incl. PSMF, SOPs and safety agreements) as well as safety related regulatory reporting documents
- review and improvement of Santhera's System for Pharmacovigilance (incl. presentation of the Santhera PV System and its performance in audits and inspections)

The Drug Safety Operations Lead participates in a wide range of cross-functional teams and works closely with internal Development functions such as DRA, Clinical Operations, Clinical Science, Biostatistics, QM as well as Medical Affairs and Commercial. The role also closely interacts with external partners and pharmacovigilance vendors such as distributors, licensing partners, DSMB, Assigned Pharmacovigilance Centre, Medical Information Service Provider.

Key Responsibilities

- Oversee the production of the complete safety data sets that are required for performing periodic and ad-hoc reviews of safety data in the context of signal monitoring and reporting to health authorities. Ensure this data set is reconciled with sources from which they are obtained, as needed, and is Quality Controlled.
- Lead data searches in Santhera's Global Safety Database as required.
- Manage MedDRA and WHO DD updates and licence renewal.
- Lead safety data management activities, own the Santhera drug safety data entry conventions, data management related SOPs, oversee search strategy management and vetted database output provision.
- Oversee and participate in planning and execution of validation activities with support of the safety database vendor and managed services provider under the supervision of QM together with the CSV Lead.
- Act as single point of contact for the main drug safety service providers. Coordinate and approve their activities, sign off on deliverables, measure vendor performance. Run regular vendor governance and vendor compliance monitoring.

- Support GH DS&PV in continuous optimization of the PV eco-system, enabling efficiency increase through process innovation, automation and other technologies and tech enabled services.
- Produce the monthly and quarterly Signal Detection reports, coordinate the review and archiving of these reports.
- Participate in special PV projects such as major company PV changes related to PV vendor, safety database etc. and where required lead such projects in agreement with the GH DS&PV and QM.
- Liaise with Clinical Operations to ensure adequate oversight of clinical CROs on PV related activities.
- Support the GVP QM the drafting of CAPA plan proposals as response to audit & inspection findings, safety related Deviations and safety process Problem Notifications.
- Participate in safety audits and inspections and support overview of CAPA plan execution and closure.
- Participate in operational cross-functional teams where DS&PV operational presence is needed.
- Support the GH DS&PV and the EU QPPV in the further development of the Drug Safety System and keeping this system in compliance with global regulatory requirements in areas where Santhera is active.
- Responsible for Business Continuity management and oversight of the Drug Safety System, participate in BCP testing and assume BCP designated role as per crisis scenarios.

Required Qualifications & Experience

- Mandatory scientific education (master's degree or equivalent), in life sciences (such as pharmaceutical sciences, biology, medicine, biomedical sciences)
- Minimum 5 years of experience in an operational Drug Safety role (preferred)
- PV training received and diversity of PV aspects addressed in previous PV roles
- Relevant experience in at least two of the following major drug safety operations areas (case management (incl. follow-up and reconciliation), safety database management, safety agreements, affiliates local PV, PV system master file / PV compliance, vendor management)
- Good knowledge of European and US Drug Safety and Pharmacovigilance requirements, knowledge in other geographical areas is a plus
- Good knowledge of Drug Safety/Pharmacovigilance practices and tools (e.g. LSMV, LSRA, Argus Database, signal / other reporting tools)
- Fluent in English, both written and spoken; additional language skills are advantageous

Required Competencies & Skills

- Attention to detail and quality oriented
- Good medical and scientific judgement
- Excellent communication, interpersonal and networking skills
- Ability to work independently and collaboratively, as required, in a matrix environment
- Excellent time management, planning and organizing skills
- Proactive attitude, accountability
- Flexibility to adapt to changing priorities and deadlines

For this position, the relevant working/residency permit or Swiss/EU-Citizenship is required.

If you are interested in a multicultural, challenging, and innovative working environment and your profile matches our requirements, we are looking forward to receiving your online application in English via LinkedIn or email, at career@santhera.com

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