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:

Physician, Drug Safety & Pharmacovigilance

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

Scope of Work

This position aims to put in place a role of senior global medical expert concerning the safety and risk profile of assigned products. It participates in and where applicable takes global leadership of operational, governance and advisory aspects of the medical management of safety data and the related drug safety, risks and benefit-risk profiles of assigned products. It ensures:

- Adequate medical management of individual case reports (ICSRs)
- Providing Global Medical Safety Expertise for assigned product(s)
- Delivering contribution and advice as global drug safety expert for assigned products to Drug Safety Governance meetings and various other cross-functional team meetings

The scope of work of this position also includes the contribution to the efforts for continued optimisation of Santhera PV Systems.

The responsibilities for this role include the following:

A. Medical management of individual case reports (ICSRs)

- QC of ICSRs from a medical perspective, QC of MedDRA coding
- Medical evaluation of ICSRs, including causality assessment, interpretation of ICSRs in the context of cumulative safety data, identifying cases of special interest, identifying cases needing immediate escalation within the Santhera Drug Safety and Pharmacovigilance governance structures.
- Provide guidance on event selection and (MedDRA) coding (event, indication, drug) at individual case level and ensure related compliance with concerned current regulatory requirements. Ensure consistency of case handling from a medical perspective and of MedDRA coding across cases to enable effective and efficient data retrieval.
- Provide sponsor/MAH input into and guidance on the follow-up on ICSRs with the reporter(s), into the expectedness/listedness of the events according to the applicable RSI and into the company's causality assessment and company case comments.
- Provide sponsor/MAH input and guidance on case closure decisions

Extra complexities:

- Tasks to be performed in collaboration with third party (UBC) to whom the operational case management and processing has been outsourced.

- The target is that the candidate within the first year after assignment succeeds in moving the currently outsourced medical management part of the routine operational processing of ICSRs into the company.

B. Provide Global Medical Safety Expertise for assigned product(s)

- Present and discuss product safety data at Santhera's Drug Safety and Pharmacovigilance governance bodies (Safety and Signal Management Teams, Drug Safety Board, Drug Safety Monitoring Boards)
- Develop and maintain up to date medical knowledge on the assigned products and in particular on the safety aspects of these products and their benefit-risk ratio
- Develop and maintain up to date medical knowledge of the populations treated with the assigned products, with particular relevance to the assessment and interpretation of safety information reported in association with the use of assigned products in these populations and the particular risks existing in the populations.
- As Global Medical Safety Expert for assigned products:
    - review and provide feed-back on signal detection (SD) reports that are prepared by PV service provider (UBC) and support SD activities for instance by reviewing aggregate data and data listings. Support MAH responsibilities for Eudravigilance monitoring relative to SD for assigned products when this will become operational and mandatory in 2018.
    - review and co-author regulatory documents such as RMP, REMS, PBRER/PSUR, DSUR, Annual Reassessment Reports, and other
    - maintain the CSI up to date
    - review and co-author responses to regulatory enquiries, requests for supplemental information, (preliminary) assessment reports received from the regulatory authorities, and other
    - review clinical study documentation such as Investigator's Brochures, Clinical Study Protocols, Informed Consent Forms, Safety Management Plans, Statistical Analysis Plans, Dear Investigator Letters, Clinical Study Reports, and other
    - review and contribute to – including co-authoring of safety sections as needed - Regulatory Affairs documents such as application files, safety variations, annual re-assessment reports, renewal dossiers, Direct Health Care Professional Communications (DHPC), Educational Materials, SmPC, PIL, USPI, and other
    - review and contribute to – including co-authoring of safety sections as needed – Medical Affairs documents such standard response documents, Product Manuals, Product Information Leaflets, Manuscripts for Publications.

Extra Complexities:

- The Drug Safety Physician as global Medical Safety Expert for assigned products needs to be able to well collaborate closely in a matrix type setting with the Clinical Research Physician and define the common company positions regarding matters of drug safety and pharmacovigilance as proposals for review and approval by the Santhera Drug Safety Board.

C. Contribution to Drug Safety Governance meetings and various other cross-functional team meetings

- Permanent Member and Chair of Santhera's Safety and Signal Management Assessment Team(s) for assigned product(s). Coordinate and actively participate in related activities.
- Ad-hoc member of Santhera's Drug Safety Board (DSB). Presents safety data to the DSB when attending the meeting and participates in the discussions during such meetings.
- Participant to the monthly meetings with UBC
- Presents safety data at the Drug Safety Monitoring Board meetings where required and only if the presented data can remain blinded and/or arise from open label studies.
- Serve as Delegate for Santhera HDS&PV at various meetings, in case of unavailability of the HDS&PV. Examples: Grants and Special Supply Assessment Team meetings, meetings to review the support to Investigator Initiated Trial applications, Drug Safety Board meetings, Operational Management Team meetings organised by Clinical Development Teams.

D. Contribute to the efforts for continued optimisation of Santhera PV Systems

- Provide suggestions for modification and/or optimisation of the medical handling of ICSRs at Santhera where possible or needed.
- Make proposals for new of modified methods and standards for SD where possible or needed to respond to evolutions in regulatory requirements concerned
- Contribute to the maintenance of Santhera's list of 'always serious' medical events
- Ensure procedures are in place to meet the MedDRA coding targets as specified above under the responsibilities related to medical management of ICSRs.

Required background and experience:

- Medical Doctor
- At least 3 years relevant experience in industry in medical drug safety and pharmacovigilance roles or medical clinical research roles with inclusion of medical management of the drug safety aspects of the investigational drugs.
- Very good knowledge of European regulatory requirements regarding drug safety and pharmacovigilance and well acquainted with standard safety and Benefit-Risk type of regulatory reports and documents such as PSURs/PBRERs, DSURs, RMPs, Annual Assessment Reports, Compassionate Use Reports, and other.
- Good knowledge of similar regulatory requirements in US and similar standard safety and Benefit Risk Reports in US. Similar experiences in other regions will be considered as an extra asset.
- Excellent knowledge of MedDRA terminology and coding
- Experience with Signal Detection and signal management activities. Good analytical skills.

Required competencies and skills:

- Excellent communication, interpersonal and networking skills
- Self-motivation, able to work independently as well as on cross-functional teams
- Team player with good organisational skills and able to successfully lead teams and small projects.
- Excellent knowledge of English (understanding, speaking and writing) and good communication skills.
- Appropriate ethical standards
- Patient focus, oriented to successfully defend and safeguard the patient's interests at all times and circumstances.

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.