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:

Head Drug Safety and Pharmacovigilance (DS&PV)

Location: Pratteln, Switzerland (Hybrid)

Scope of Work

We are looking for an experienced and strategic leader to join our team as Head of DS&PV. In this role, you will oversee Santhera's global PV systems, ensuring compliance with all PV and Quality obligations as a marketing authorization holder and clinical trial sponsor. You will maintain an overview of the safety profiles for all authorized and clinical-stage products.

You will also provide guidance on drug safety in development programs, including input on IBs, IMPDs, protocols, and the company's core safety information data sheet. Additionally, you will ensure adequate support and resources from the CEO and General Managers. This role reports to the Chief Medical Officer.

Key Responsibilities

- Oversee Santhera's global Pharmacovigilance (PV) system, ensuring compliance with regulations and managing PV vendors and activities.
- Ensure Santhera meets its obligations as a clinical trial sponsor and marketing authorization holder, maintaining a robust PV framework.
- Monitor drug safety across all products, ensuring timely identification, escalation, and management of safety concerns.
- Oversee the execution of QPPV responsibilities, ensuring compliance with EU and global regulatory requirements, including validation oversight.
- Supervise risk management systems, the implementation of risk minimization measures, and the oversight of PASS/PAES studies.
- Ensure high-quality safety reporting, including PSURs, Risk Management Plans, and timely submissions to health authorities.
- Maintain oversight of company core safety information (CCSI), ensuring it reflects current scientific knowledge and regulatory recommendations.
- Collaborate with regulatory teams to address safety-related regulatory actions and respond promptly to health authority requests.

Required Qualifications & Experience

- Medical, Scientific or equivalent Degree
- At least 10 years of experience in all aspects of drug safety and pharmacovigilance (clinical development and post marketing)
- Expert knowledge of European and US Drug Safety and Pharmacovigilance requirements and strong knowledge in other geographical areas
- Expert knowledge of Drug Safety/Pharmacovigilance practices and tools (e.g. Argus Database)

Required Competencies & Skills

- Strong leadership skills to represent DS&PV at the company level and communicate key issues and opportunities effectively.
- Agile and flexible mindset to set priorities and work efficiently within a small company.
- Excellent planning, organization, and time management skills to meet tight deadlines in a fast-paced environment.
- Strong verbal and written English communication skills, with attention to detail and a quality-oriented approach.
- Ability to work independently while being a reliable team player, managing multiple projects in a matrix environment.

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

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

Strictly no agencies: Recruitment agencies are kindly invited to refrain from sending unsolicited CVs to Santhera.