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:

GVP QA Manager

Location: Pratteln, Switzerland (Hybrid)

Scope of Work

As a GVP QA Manager at Santhera, you will play a crucial role in maintaining and enhancing our global Pharmacovigilance (PV) System. Your work will ensure that Santhera meets its legal PV obligations as both a Marketing Authorization Holder and a Sponsor of clinical trials.

In this role, you will help strengthen oversight, improve processes, and maintain compliance with international regulations. You will facilitate the implementation of high-quality PV procedures, support audits and inspections, and collaborate with internal and external stakeholders to ensure a robust and effective PV System.

Please note: We are open to considering candidates who prefer a part-time arrangement (minimum 50**%** workload). If you are interested in a part-time role, please indicate your preferred working hours in your application.

Key Responsibilities

- Continuously review and improve Santhera's global PV System.
- Ensure timely release and updates of PV procedures, including oversight of training completion.
- Oversee PV procedures and standards at both global and local levels.
- Act as Santhera's PSMF Coordinator.
- Contribute to the annual PV Audit Plan and implement necessary updates.
- Support PV-related audits, third-party assessments, and regulatory inspections.
- Draft and oversee CAPA plans to address audit findings, inspections, and deviations.
- Monitor and manage the execution and closure of CAPA plans.
- Identify and escalate overdue CAPAs or those at risk.
- Track and analyse GVP-related KPIs, contributing to Santhera's Quality Council.
- Assist in the development, review, and maintenance of PV Agreements and Service Agreements with vendors.

Required Qualifications & Experience

- Minimum 2 years of experience in international Pharmacovigilance.
- Strong knowledge of quality systems and PV compliance.
- Experience with PV audits and/or regulatory inspections.
- Deep understanding of European Drug Safety and Pharmacovigilance requirements (global knowledge is a plus).
- Fluent in English (written and spoken); additional languages are an asset.

Required Competencies & Skills

- Strong attention to detail and commitment to quality.
- Excellent communication, interpersonal, and networking skills.
- Ability to work independently and collaboratively in a matrix environment.
- Strong time management, planning, and organizational skills.
- Proactive, accountable, and adaptable to changing priorities.

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 email at career@santhera.com.

Note for External Staffing Agencies or Recruiters: *External Staffing Agencies or recruiters are kindly invited to refrain from sending unsolicited resumes to Santhera. The submission of unsolicited resumes in advance of an agreement between the People & Culture Department and the external staffing agency or recruiter does not create any implied obligation on the part of Santhera.*