



Santhera Pharmaceuticals is a Swiss specialty pharmaceutical company committed to developing and commercializing innovative medicines to meet the needs of patients living with rare and other diseases with high unmet medical needs.

At Santhera, our people are the driving force behind our success. Our collective loyalty, courage, and resilience set us apart and help us thrive through change as a collaborative team. We create a purposeful workplace where your contribution matters, growth is fostered, and together we make a real impact for those living with rare diseases and for each other.

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:

## Senior GVP QA Manager

Location: Pratteln, Switzerland (Hybrid)

### Who you are

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You are a collaborative and proactive quality professional with solid experience in pharmacovigilance and a strong understanding of GVP compliance and quality systems. You enjoy working in dynamic environments where processes and structures continue to evolve, and you are motivated by the opportunity to help build and strengthen scalable QA oversight frameworks.

You bring a hands-on mindset combined with the ability to work strategically across multiple stakeholders, affiliates, and external partners. You are comfortable navigating complexity, driving improvements, and ensuring high quality and compliance standards in a growing international environment.

### Scope of Work

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The Senior GVP QA Manager is responsible for supporting the maintenance and continuous improvement of the global Pharmacovigilance (PV) System to ensure that Santhera fulfils its legal PV obligations as both a Marketing Authorisation Holder (MAH) and Sponsor of clinical trials.

The role supports PV oversight activities, process improvement initiatives, and compliance with applicable global regulatory requirements.

Responsibilities include supporting the implementation and maintenance of PV procedures and the PV audit programme, including the planning, coordination, execution, and follow-up of internal and external PV audits, contributing to inspection readiness activities, and collaborating with in-ternal and external stakeholders to support effective oversight and ongoing compliance of the PV System.

### Key Responsibilities

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- Assisting with the continuous review and improvement of Santhera's PV System
- Ensuring timely release of new PV procedures, or updates of existing PV procedures, as needed.

- Ensuring oversight of completion of related PV training requirements with input from the line managers of staff needing training.
- Facilitating oversight of the applied PV procedures and standards at global and local level.
- Creating and providing input into Santhera's annual PV Audit Plan and ensuring ad-hoc updates are made should these become needed.
- Carrying out or supporting PV related audits that Santhera conducts internally or to third parties, including PV qualification audits.
- Supporting PV related audits of Santhera conducted by third parties and PV inspections by Regulatory authorities.
- Supporting the drafting of CAPA plan proposals as response to audit findings, inspection findings, safety related deviations.
- Approval of GVP quality events (CAPAs, deviations, quality controls).
- Supporting overview of CAPA plan execution and closure.
- Ensuring the proper presentation of audit and inspection findings and CAPAs in the PSMF, including their status. Contributing to sections of the PSMF as required by Drug Safety and Pharmacovigilance (DS&PV).
- Maintaining the audit trail of CAPA plans with PV relevance and creating living overview of their status of executional progression and completion.
- Signalling overdue CAPAs or CAPAs at risk to the GCP & GVP QA Lead, Head of DS&PV and EU/UK Qualified Person for Pharmacovigilance.
- Supporting the monitoring of GVP related KPIs; providing input on GVP related KPIs and other GVP related Quality Matters to Santhera's Quality Council

The job holder has the responsibility to train and comply with Quality Documents as per Santhera Training Matrix.

### Required Qualifications & Experience

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- At least 5 years of relevant experience in international Pharmacovigilance with 2 years in quality assurance.
- Adequate knowledge of general standards for quality systems
- Experience with PV audits and/or inspections
- Good knowledge of European Drug Safety and Pharmacovigilance requirements, but by preference also in other geographical areas
- Mandatory fluent in English (understanding, speaking and writing); any other languages are an asset

### Required Competencies & Skills

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- Attention to detail and quality oriented
- 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

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](mailto:career@santhera.com)

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