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:

Director GCP Quality Management

Location: Pratteln, Switzerland (Hybrid)

Scope of Work

We are looking for a Director GCP Quality Management to play a critical role in supporting our clinical development program and ensuring compliance with global regulations. Reporting to the Head of Quality Management, you will be a key driver in shaping and maintaining our quality culture.

In this pivotal role, you will lead GCP Quality Management activities, ensuring clinical development programs are conducted in line with regulatory requirements. You will collaborate across teams, provide expert guidance, and play a leading role in audits, risk management, and inspection readiness.

Key Responsibilities

- Design, plan, and execute risk-based GCP audit programs (internal and external).
- Provide GCP expertise to project teams and ensure Quality Management input in clinical programs.
- Lead or contribute to Quality Risk Management activities for clinical trials.
- Manage and conduct audits of internal processes, external vendors, and investigator sites to ensure compliance and identify risks.
- Oversee the development of CAPAs (Corrective and Preventive Actions) and ensure timely resolution of GCP issues.
- Establish effective communication of audit/inspection outcomes and drive continuous improvement.
- Align activities with other Quality Management functions (e.g., GVP, GMP) to ensure a cohesive approach.
- Stay ahead of emerging regulations and ensure knowledge transfer within the organization.

Required Qualifications & Experience

- Bachelor’s degree (or higher) in a relevant field.
- 5-7 years of experience in the pharmaceutical or life sciences industry, with a strong focus on GCP Quality Management.
- In-depth knowledge of FDA, EU, and ICH guidelines for clinical research.
- Proven track record managing GCP audits, health authority inspections, and inspection readiness.
- Experience in Quality Risk Management for clinical trials and implementation of quality plans.
- Knowledge of pharmacovigilance regulations is a plus.
- Excellent interpersonal and communication skills with the ability to work in a fast-paced, collaborative environment.
- Ability to travel up to 30%.
- Fluency in English (written and spoken) is required.

Required Competencies & Skills

- Strong communication and stakeholder management skills.
- Ability to work both independently and within a matrix organization.
- Strategic mindset with strong problem-solving abilities.
- Organized and detail-oriented, with excellent planning capabilities.
- Adaptability 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 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.