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:

Senior Manager GMP QA

Location: Pratteln, Switzerland (Hybrid)

Scope of Work

We are looking for a Senior Manager GMP QA to maintain and enhance Santhera's GMP compliance and Quality Assurance strategies. Reporting to the Head of Quality Management, this role oversees GMP/GDP quality projects for development and commercial-stage products. The position collaborates with internal teams, including Technical Development & Operations (TDO), Supply Chain, and Regulatory Affairs, as well as external partners, contractors, and Health Authorities.

This role ensures products (DS and DP) meet global GMP/GDP standards, internal policies, and regulatory requirements. The job holder will be responsible for maintaining the GMP/GDP Quality Management System (QMS), conducting audits, managing compliance activities, and supporting regulatory inspections.

Key Responsibilities

- Maintain and improve GMP/GDP QMS in compliance with company policies and global regulations.
- Ensure manufacturing, testing, and distribution meet cGMP requirements.
- Conduct and oversee internal and external GMP/GDP audits.
- Manage GMP/GDP SOPs and ensure regulatory alignment.
- Oversee batch record review and product release.
- Monitor and manage supplier qualifications, audits, and performance evaluations.
- Support investigations, deviations, change controls, and CAPA implementation.
- Ensure regulatory compliance by tracking industry updates and implementing necessary changes.
- Maintain the Site Master File and ensure readiness for Health Authority inspections.
- Support Quality Council meetings, KPIs monitoring, and product defect assessments.

Required Qualifications & Experience

- Bachelor's or advanced degree in pharmacy, chemistry, engineering, or life sciences.
- 7+ years of experience in the pharmaceutical/biotech industry.
- 5+ years in GMP Quality Assurance at a local or global level.
- Strong knowledge of cGMP global regulatory requirements and quality systems.
- Fluency in English (additional languages are a plus).

Required Competencies & Skills

- Strong problem-solving and analytical skills.
- Excellent planning, organizing, and time management abilities.
- Ability to work independently and manage multiple projects in a fast-paced environment.
- Reliable team player with leadership skills in cross-functional settings.
- Solution-oriented, proactive, and adaptable in dynamic situations.

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

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

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