Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular and pulmonary diseases with high unmet medical need.

Santhera has an exclusive license for all indications worldwide to vamorolone, a first-in-class dissociative steroid with novel mode of action, currently investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. The clinical stage pipeline also includes lonodelestat (POL6014) to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases as well as an exploratory gene therapy approach targeting congenital muscular dystrophies. Santhera out-licensed ex-North American rights to its first approved product, Raxone® (idebenone), for the treatment of Leber's hereditary optic neuropathy (LHON) to Chiesi Group.

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 Quality Assurance

at our Headquarters in Pratteln, Switzerland (close to Basel) on a full-time basis (100%).

Scope of Work

The role reports to the Head GMP Quality Management, acting as her deputy, and will collaborate closely with other functions such as Technical Development, Supply Chain Management and Regulatory Affairs across geographical boundaries. Externally, the job holder will collaborate with Health Authorities, contract manufacturers and other partners.

The core responsibilities are:

- Ensuring GMP/GDP quality management system, processes, specifications, and SOPs are designed and maintained to be appropriate for the development, manufacture, testing and timely release and distribution of quality products
- Support continuous improvement of Quality Systems and Compliance, support quality management review processes, annual product quality reviews, overall inspection readiness and state of control
- Ensuring products are manufactured in accordance with GMP, internal policies/procedures and applicable regulatory requirements and guidance
- Overseeing GDP related activities throughout the product supply chain, including transportation activities and customer qualification activities
- Managing and supporting GMP/GDP supplier qualification activities (e.g. performing audits, review of Quality Agreements and supportive documentation)
- Maintaining and extending technical and professional competence in support of QP responsibilities to ensure thorough understanding of any products and processes prior to the QP batch certification
- Acting as the deputy Responsible Person for Switzerland and Liechtenstein
- Supporting preparation and review of investigations, root cause analysis and review and approval of major/critical deviations, complaints and change controls with process and product impact
- Interacting with Health Authorities as it pertains to licenses and regulatory activities
- Supporting product defects and recalls assessments if needed

Required background and experience:

- Minimum Bachelor degree in a scientific discipline (e.g. pharmacy, chemistry, engineering, life science) or similar education; advanced degree in natural or applied sciences preferred
- At least 7 years relevant experience in the pharmaceutical / biotech industry
- At least 5+ years of experience in experience in Quality Assurance on a local and / or global level
- Experience in QC lab in GMP environment or Analytical Development is a plus
- Experience in release of commercial product and in GDP QA activities, or in manufacturing QA Operations. Experience in biotech or sterile products is a plus
- Thorough knowledge in cGMP global regulatory requirements and quality systems
- Auditing experience (certification by a recognized body) and / or experience in handling regulatory inspections is a plus
- Practical experience in the area of data integrity, computer system validation and electronic records and signature requirements are a plus
- Fluency in English (German or any other language is a plus)

Required competencies and skills:

- Ability to work with tight deadlines as well as strong planning, organizing and time management skills
- Attention to details, dedication to accuracy
- Reliable and with high sense of accountability
- Ability to work independently to manage multiple projects in a fast-paced environment
- Solution orientation, proactivity with energy and drive
- Personal resilience, perseverance
- Strong problem solving and analytical skills
- Reliable team-player with strong competence in leading cross-functional teams and operating within a matrix organizational structure
- Strong verbal and written communication skills

If you are attracted by this exciting opportunity and the prospects of joining a motivated international team operating on a global level, please send your CV and motivation letter mentioning the position **"GMP Quality Assurance Manager"** as the subject by email to: career@santhera.com.

Strictly no agencies

Recruitment agencies are kindly requested to refrain from sending unsolicited CVs to Santhera.