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 is building a Duchenne muscular dystrophy (DMD) product portfolio to treat patients irrespective of causative mutations, disease stage or age. A marketing authorization application for Puldysa® (idebenone) is currently under review by the European Medicines Agency. Santhera has an option to license vamorolone, a first-in-class dissociative steroid currently investigated in a pivotal study in patients with DMD to replace standard corticosteroids. The clinical stage pipeline also includes POL6014 to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases, as well as omigapil and 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 more information about Santhera, please visit the company's website www.santhera.com

We are currently looking to hire a:

QA Manager GMP

To be based in our HQ office in Pratteln, Switzerland.

Scope of Work

The role reports to the GMP Compliance Officer who is based in Pratteln, and will collaborate closely with other functions such as Supply Chain, Technical Development and Regulatory Affairs based in the HQ in Switzerland and, externally, will collaborate with contract manufacturers.

The core responsibilities are (not exclusively):

- Performance of QA operational activities (e.g. batch review)
- Maintenance and improvement of GMP/GDP Quality Management System
- Vendor audits in the GMP/GDP field
- Internal Audits
- Management and evaluation of change controls, deviations, complaints, CAPA
- Support of HA inspections and follow up, incl. preparation of CAPA
- Supporting GDP activities at SPLI, as requested
- Supporting GMP activities at SPDE, as requested

The responsibilities for this role include the following:

- Act as deputy of Responsible Person Switzerland and Responsible Person Liechtenstein
- Review and approve executed batch production records, CoAs, stability and validation protocols and reports, as required
- Revise SOPs as required
- Prepare and review quality agreements with vendors and customers
- Support qualification and oversight of vendors and customers
- Track, evaluate and follow up on CAPA, deviations, complaints and changes
- Evaluation of Product Quality Reviews
- Communication with internal and external customers as required
- Support maintenance of audit plans and documentation
- Preparation and performance of internal and external audits
- Support preparation of HA inspections and CAPA responses
- Support computerized system validation at Santhera
- Support monitoring of legal requirements

- Support KPI evaluation
- Support SOP maintenance as required (formal review, issuing, uploading in LMS etc.)
- Write and review of CMC parts of regulatory submissions

Required background and experience:

- University diploma in Natural Sciences or equivalent
- Minimum 8 years of experience in a regulated environment (pharma, medical devices or nutritionals)
- Minimum 5 years of experience in a GMP area, preferably in QA/QC
- Minimum 2 years of experience in QC lab in GMP environment is a plus
- Good understanding of pharmaceutical manufacturing processes, quality control testing methods and quality system requirements
- Experience in handling regulatory inspections is a plus
- Fluency in German and English is mandatory
- Experience in CMC technical writing is a plus
- Qualification as EU QP not required but would be a plus
- Auditing experience (certification by a recognized body is a plus)

Required competencies and skills:

- Excellent communication and interpersonal skills
- Team player, able to work independently as well as on cross-functional teams
- Excellent time management
- Very well structured, organized
- Flexible in adapting to changing priorities and deadlines
- Attention to details, dedication to accuracy
- Reliable and with high sense of accountability
- Self-motivation, proactive attitude, solution oriented
- Personal resilience, perseverance, energy and drive

If you are interested to apply for this role, please send your application by email at career@santhera.com

Strictly no agencies

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