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

Quality Associate Batch Record Review (100%)

Location: HQ Pratteln (CH)

Scope of Work

The Quality Assurance (QA) Batch Record Reviewer is responsible for preparing the technical and final release of our products. The QA Batch Record Reviewer performs functions necessary to ensure that all relevant manufacturing records are compiled, reviewed and completed in a compliant and efficient manner. This position requires attention to detail and must be performed in accordance with standard operating procedures and all applicable regulatory and GMP requirements.

Key Responsibilities:

Responsible for meeting assigned goals in technical and final release review including, but not limited to:

- Review, and verify executed batch records of APIs, Drug Products and secondary Packaging
- Review analytical batch records
- Confirm the relevant quality control results are within acceptable limits.
- Review and complete records ensuring compliance with applicable SOPs and regulatory regulations.
- Communicate with CMOs on missing documentation and error corrections
- Archiving of the entire batch documentation
- Responsible for reporting all variances, errors and deviations to Quality Assurance.
- Manage Records in e-systems (e.g. Veeva systems)
- Able to collaborate on complaint and/or nonconformance reports according to Santhera procedure.
- Performs other duties as assigned by the line management

Required Background and Experience:

- Minimum of three years' experience in quality assurance and GMP in the pharmaceutical / biotech industry is preferred
- 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
- Enhanced Computer skills
- Proficient in German and English

Required Competencies:

- 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
- 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

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 email at career@santhera.com

Strictly no agencies:
Recruitment agencies are kindly invited to refrain from sending to Santhera unsolicited CVs.