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 CSV Quality Systems

Location: HQ Pratteln (CH), Hybrid

Scope of Work

The Senior Manager CSV Quality Systems is responsible for ensuring that all GXP computerized systems used in Santhera comply with relevant regulations and guidelines.

This role involves planning, coordinating, and executing validation projects to ensure data integrity, system reliability, and regulatory compliance.

Responsibilities include, but are not limited to:

- Oversight of Santhera's GXP Computerized Systems.
- Collaborate with QM and other internal stakeholders (e.g. IT) to ensure that validation activities are aligned with overall quality objectives.
- Support cross-functional teams in the implementation and validation of computerized systems.
- Conduct or participate in internal and external CSV related audits.
- Provide training and guidance to staff on validation procedures and regulatory requirements.
- Maintain, develop, and implement validation strategies and plans for GXP computerized systems in accordance with regulatory requirements (FDA, EMA, etc.).
- Establish and maintain validation documentation, including Validation Master Plans (VMP), risk assessments, protocols, and reports.
- Lead and coordinate the validation of new and existing computerized systems, ensuring they meet GMX requirements.
- Perform risk assessments and define validation activities based on system impact and criticality.
- Ensure the conduct of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) testing.
- Ensure compliance with applicable regulations, guidelines, and standards, including 21 CFR Part 11, GAMP 5, and Annex 11.
- Stay current with industry best practices and regulatory changes to maintain compliance and improve validation processes.

The job holder has the responsibility to train and comply with the Quality Documents indicated in the Santhera Training Matrix.

Required Background and Experience:

- Bachelor's degree in Computer Science, Engineering, Life Sciences, or a related field. Advanced degree preferred.
- Minimum of 5 years of experience in CSV and GMP within the pharmaceutical or biotech industry.
- In-depth knowledge of GXP and ICH requirements and guidelines and 21 CFR Part 11 regulations and GAMP 5 and Annex11 requirements for computerized systems.

Required Competencies:

- Excellent communication skills (e.g., listening skills, ability to interpret and summarize information and clear and concise verbal communication skills).
- Strong project management, analytical, and problem-solving skills.
- Strong organizational skills, with the ability to effectively prioritize and manage multiple projects and tasks, with attention to detail.
- Strong interpersonal skills and the ability to assist personnel in a fast-paced environment and the ability to proactively resolve issues in a diplomatic, flexible, and constructive manner.
- Highly ethical, self-motivated, and self-directed; works effectively independently as well as in a team environment.

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 application in English via email at career@santhera.com

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