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 Drug Regulatory Affairs

Location: HQ Pratteln (CH), Hybrid

Scope of Work

The Senior Manager Drug Regulatory Affairs reports to the Head Drug Regulatory Affairs who is based in Pratteln and will collaborate closely with other functions such as Clinical Operations, Clinical Sciences, Pharmacovigilance, Biostatistics, Preclinical or CMC, based in the HQ in Switzerland.

The role is responsible for leading some global regulatory activities, including operational and strategic activities in drug development, registration and post-marketing phases.

Responsibilities include, but are not limited to

- Provision of regulatory input and support to Post-Approval Regulatory procedures in EU and ROW (document quality and accuracy, coordination of input from other line functions, coordination of the submission process):
  - Variations
  - PSUR
  - MA Annual Re-assessment
  - Scientific advice
  - Preparation of meetings with HA
  - Pediatric investigational Plan

- Clinical Trial Authorisation applications and maintenance:
  - Preparation and submission for regulatory approval of clinical trial authorisation applications
  - Maintenance of existing clinical trial authorisations: Preparation and submission of amendments and the notification of start of trial and end of trial as required.
  - Input in decision process regarding clinical trials conduct and strategy
  - Supervises regulatory CRO counterpart as applicable
  - Communication with Regulatory Authorities in relation to CTA topics
  - Study Management Team membership: provides necessary regulatory guidance and support to the SMT

    - Support DS&PV for the preparation and submission of the DSUR

- Critical review of documents:
    - Ensures the accuracy, scientific validity and optimal presentation of applicable regulatory documents (IB, Protocol, IMPD etc)

- Regulatory Intelligence:
    - Identify appropriate guidance, regulations and sources for regulatory compliance

- Document management:
    - Filing and archiving the regulatory documents according to SOPs
    - Maintenance of electronic filing systems and internal regulatory archive

- Other Regulatory activities, as applicable

Required Background and Experience:

- Mandatory previous experience in a pharmaceutical company or a CRO.
- Minimum bachelor's degree in life science.
- Minimum 8 years of experience in a similar role in Regulatory Affairs.
- Experience in clinical trial applications.
- Knowledge of EU/US clinical trials guidelines & regulations.
- Previous experience in operating within complex matrix organizations.
- Fluency in English, both written and oral.

Required Competencies:

- Excellent communication, interpersonal and networking skills.
- Self-motivation, personal resilience, perseverance, energy and drive.
- Ability to work independently and collaboratively, as required, in a matrix organization.
- Excellent planning and organizing skills.
- Flexibility in adapting to changing priorities and deadlines.
- Capable of dealing with ambiguity, risk taking and decision making in a fast-paced entrepreneurial environment.
- Open minded, solution oriented.

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 at career@santhera.com

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