



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, which was investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. The Company plans to complete the ongoing rolling submission of its filing for approval for vamorolone with the US FDA in Q2-2022. The clinical stage pipeline also includes lonodelestat to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases. Santhera out-licensed rights to its first approved product, Raxone® (idebenone), outside North America and France 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:

Associate Director, Medical Information and Operations

Based out of our Burlington, Massachusetts office on a full-time basis (hybrid work).

Scope of Work

Reporting to the VP, Medical Affairs, North America, and working in close collaboration with Santhera colleagues across functions as well as external partners, the AD, Medical Information and Operations plays a key role in planning, building, delivering, and managing key operational and content capabilities supporting the Santhera Medical Affairs function.

The incumbent is accountable for the enablement and successful delivery of core medical affairs capabilities, including but not limited to: medical information, MLR medical review, medical content development, medical training, and others. This role is also accountable for building and managing the medical operations infrastructure intended to drive effectiveness, efficiency and compliance, inclusive of budget management and KPI reporting.

These capabilities are in constant evolution to meet opportunities and challenges; therefore, the incumbent is accountable for proactively identifying needs, as well as recommending, designing and implementing ways to meet them.

This is a complex function, operating in a complex healthcare and compliance environment. Success in this role requires close collaboration with a number of functions at Santhera including: Clinical, Commercial, Regulatory, Compliance, IT, Finance, and others, as well as specialized external partners.

The core responsibilities are:

- Working closely with the VP. Medical Affairs, ensure the Medical Affairs function operates effectively, efficiently and compliantly.
- Develop and maintain current the Santhera medical information strategy and plans, in alignment with global medical strategy.
- Develop and maintain medical content and materials to address unsolicited requests for medical information including standard response letters, customized responses, and frequently asked questions.
- Develop and maintain medical content for proactive and/or reactive delivery of medical content by the Medical Affairs team to relevant audiences, including KOLs and payors.
- Develop and maintain relevant content for presentation at Advisory meetings and other advice-seeking activities.
- Develop and maintain relevant medical content for presentation and/or display at congresses.
- Provide oversight for all activities related to the provision of accurate, scientifically sound, and timely responses to unsolicited inquiries from HCPs and other stakeholders.
- Oversee engagement with external medical information and communications vendor(s) and ensure operational excellence in their effort, e.g., call-center operations, reporting, training, as well as compliance monitoring and corrective actions when required.
- Manage tracking of medical plan execution, and identify course corrections and action plans/remediation strategies as identified.
- Lead and direct medical information presence at congresses in conjunction with other relevant medical and cross-functional roles.
- Manage budget and reconciliation of the medical affairs budget with Finance.
- Serve as principal medical reviewer for MLR, and coordinate any ancillary assistance, particularly in anticipation of heavy review volume and urgent review requests.
- Lead and evolve medical affairs training, ensuring both currency of content, and conversancy of all medical staff on current and emerging data.
- With medical affairs leadership, contribute to the development of materials for external dissemination and delivery, including slides, infographics and posters, and ensure incorporation of medical narratives and messaging in content.
- With VP medical affairs and function heads, identify and define operational solutions (e.g., Veeva) to enable smooth and fluid operations across medical affairs.
- Maintain a high level of expertise of current and emergent data relevant to Santhera science and product(s).
- Is fully accountable for compliance with all laws, regulations and policies that govern the conduct of Santhera activities. As a manager of others, including external partners, the incumbent is not only accountable for their own compliance, but also for the that of all individuals in their team. As such, leads the way and leads by example by demonstrating full knowledge and commitment to all applicable policies.
- Requires up to 15% travel within North America and 5% travel internationally.

Required competencies:

- Deep clinical knowledge and an ability to learn new science rapidly.
- Expertise and training in medical information/content development and delivery.
- Ability to communicate clinical and scientific information clearly and with conviction.
- Deep knowledge of the regulatory landscape for pharmaceutical products.
- Proven strong strategic and analytical abilities.
- Strong ability to manage external service providers.
- Comfort with and ability to input and track activities and relevant key performance indicators.
- Ability to creatively solve problems with an appropriate sense of urgency.
- Ability to take incomplete and ambiguous information to develop and execute strategies.
- Strong people and organizational skills, including ability to influence decisions.
- Excellent written and verbal English communication skills.
- Team player, collaborator, flexible and highly adaptive to change.
- Exceptional communication skills. Effective in front of all teams, including scientific audiences and executive leadership.
- A passion for serving patients and their unmet medical needs.

Required background and experience:

- PharmD, PhD or equivalent required.
- 3+ years' experience in life sciences, including experience in relevant medical affairs activities consistent with job expectations.
- Experience in areas of rare diseases, neurology, pulmonology or other innovative and complex specialty conditions and therapies is strongly preferred.
- Experience in medical information, including significant authorship of standard response letters.
- Experience in participating in MLR processes.
- Experience in building and enhancing medical operations capabilities is desirable.
- Comfort and aptitude for driving and managing solutions involving information technologies.
- Experience with rare and ultra-rare diseases, especially in a launch setting is highly preferred.
- Highly skilled in influencing cross-functional teams, including interfacing with key internal and external stakeholders and with scientific and commercial teams.
- Demonstrated functional management skills.
- Demonstrated project management 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 “**AD Medical Information and Operations**” as the subject by email to: careersNAM@santhera.com.

Santhera Pharmaceuticals is committed to creating a diverse workforce and providing equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, sex, sexual orientation, gender identity, gender expression, parental status, national origin, age, disability,

citizenship status, genetic information or characteristics, marital status, status as a Vietnam era veteran, special disabled veteran, or other protected veteran in accordance with applicable federal, state and local laws, and any other characteristic protected by law.

Strictly no agencies

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