ASCELIA PHARMA

Senior Medical Writer

Do you want to be part of Ascelia Pharma – an ambitious, young, and dedicated Malmö based orphan-oncology life science company? Are you motivated by communicating scientific or medical information in a clear and concise manner?

We are looking for a Senior Medical Writer who will take a leading role in authoring complex regulatory, clinical and safety documents for orphan oncology drugs in development and join our journey in building and growing the company aiming at improving the lives of patients with rare oncology related diseases.

With direct report to the Regulatory and QA Director you will be responsible for developing and authoring meeting packages, clinical overviews and summaries targeted for global submission with focus on the FDA, EMA and the PMDA. You will be a key player in a fast-growing cross-functional team and work closely with the Chief Medical Officer and the Project Director and Head of Preclinical Development and colleagues across the organization.

Ascelia Pharma is a life science company focused on orphan oncology. We develop and commercialize novel drugs that address unmet medical needs and have a clear development and market pathway. We have two drugs in clinical development and aim to further expand our drug pipeline in therapeutic areas that leverage our unique expertise in taking orphan oncology drugs through clinical stage development and commercialization.

Your main tasks

- Authors complex regulatory clinical documents (e.g. high-level clinical summary documents), and other documents (e.g. Investigator's Brochure), in accordance with ICH, GLPs, and GCPs guidelines, for timely submission to Health Authorities or other required entities
- Participates and/or leads document prototyping sessions including the design of data displays, document flow, logic and consistency for assigned documents
- Ensures that all assigned documents support the full development strategy to achieve target labeling objectives and timely approvals in key markets
- Provides input to clinical study design, protocols and study material
- Participates in relevant regulatory team, clinical team or cross-functional team discussions and ensures effective planning and management of timelines for all components of assigned documents
- Documents and implements consensus at meetings of determined data interpretation and key findings/messages
- Performs detailed and thorough quality reviews to ensure data integrity, internal content consistency, completeness on a wide range of regulatory deliverables (CSRs, IB/Updates, CTDs, non-clinical reports, etc)
- Other duties, as assigned.

Your qualifications

To master the position as Senior Medical Writer, you need a track record in medical writing from a pharmaceutical company.

You hold MD, PharmD, PhD or other doctoral-level degree and minimum 2 years of related pharma/biotech experience or Bachelor's degree with 6 to 8 years of related pharma/biotech experience and have:

- Preferred medical writing experience with document types applicable to late phase drug development, with experience in management of complex medical writing projects
- Experience with data and documentation requirements for regulatory meetings and submissions to the FDA, EMA and other agencies, e.g. clinical evaluation reports and literature summaries
- Experience with clinical and medical language
- Ability to work with mathematical concepts such as probability and statistical inference
- Strong understanding of GxP and ICH guidance's in the pharmaceutical environment
- Demonstrated an outstanding command of the English language (read, write, and speak)
- Work permit allowing you to work in the EU.

As a colleague, professional and leader you have:

- Excellent written communication skills and strong critical thinking
- Demonstrated ability to communicate scientific or medical information in a clear and concise manner
- Strong analytical, scientifically driven and problem-solving skill
- Ability to collaborate within a team to set ambitious goals, write regulatory and clinical reports, resolve issues in scientific and industry-standard terms, as required
- Strong relationships with co-workers of various backgrounds and expertise
- Excellent organizational and time management skills with ability to set own priorities in a timely manner
- Demonstrated flexibility, integrity, and ability to deal with complexity under pressure. Must be able to work as needed to meet tight deadlines and at peak periods
- A positive attitude and optimistic outlook
- Proficient with imaging procession, bibliographic and e-publishing programs Microsoft Word, Excel, and PowerPoint, preferred
- Are excited about the Ascelia Pharma's product portfolio and opportunities ahead.

Travelling: some travelling will be required.

Work location: Preferably able to work primarily from the head office; other locations considered depending on the candidate.

Domicile: Hyllie Boulevard 34, 215 32 Malmö, Sweden

At Ascelia Pharma, your skills, dedication and engagement help us improve the lives of people living with cancer. We offer you an opportunity to be part of a fast-growing company with global reach, where engagement, dedication and results are met with opportunities for individual and professional development.

Join us on our journey to improve patients' lives and build a global orphan oncology life science organization.

How to apply

Please submit your resume and cover letter via the form below, along with any other material. Preferably apply as soon as possible but not later than **5 March**. All applications must be in English and are treated confidentially.

For more details about the job or the company, please contact:

Marie Källström

Regulatory and QA Director
Phone+46 (0)735 17 91 20

Or

Carl Bjartmar
Chief Medical Officer
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About Ascelia Pharma

Ascelia Pharma is a biotech company focused on orphan oncology treatments. We develop and commercialize novel drugs that address unmet medical needs and have a clear development and market pathway. The company has two drug candidates – Mangoral and Oncoral – in clinical development. Ascelia Pharma has global headquarters in Malmö, Sweden, and is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com.

About Mangoral

Mangoral (manganese chloride tetrahydrate) is a novel oral contrast agent for MR-imaging developed to improve the detection and visualization of focal liver lesions (including liver metastases and primary tumors) in patients with reduced kidney function. These patients are at risk of serious side effects from the currently available class of gadolinium-based contrast agents. Mangoral, which has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA), is currently in Phase 3 development, including the global multi-center SPARKLE study.

About Oncoral

Oncoral is a novel irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily tablet with the potential to offer better patient outcomes with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital. Following successful Phase 1 results, Oncoral is now prepared for Phase 2 clinical development.