Senior Medical Writer

Role

Azur Health Science are looking for a dynamic, independent **senior medical writer** to join our growing team. We need someone who is an experienced team-player and who understands the dynamics of working in a small team. You will be someone who is flexible and willing to let people learn and lead in their own way and integrate into our culture, whilst driving forward our day-to-day business.

Location: France, Mulhouse, home or hybrid working

Contract: Full-time, CDI, cadre – 35 hours/week

Teamship

As a Senior Medical Writer you are the focal point of a cross-functional project team that has the combined aim to produce a high quality document to inform a specific target audience. This target audience could be clinical study teams, ethics committees, regulatory agencies, clinical trial patients, or scientific professionals in the field. This is an important role in the process of bringing novel products to market and monitoring the safety and effectiveness of marketed products in the real world. The senior medical writer's role requires proactive diplomacy to manage the requirements of the project team as well as to manage the project itself.

Responsibilities and Accountabilities

Working with Azur, you will be required to actively contribute to the development of our team based on the foundational ethics and values of the company. Azur was founded on the principle of Teamship where there is a shared accountability and where everyone has an equal voice.

As a member of the Azur team, we expect you to respect all individuals of the team and to celebrate successes together with us, as well as being willing to share from your mistakes, in order that we might learn as a team.

The Azur team provides your learning and support network. While we expect you to take ownership and accountability of your projects, you must never work in isolation,

and you must communicate regularly with the Azur team about the progress of your project. Your ultimate accountability lies with Azur Health Science.

Your experience:

- 5-10 years of experience in regulatory medical writing, actively writing documents.
- Worked on ≥ 2 FDA or EMA submissions for marketing authorisation, ≥ 5 protocols, ≥ 3 CSRs, and ≥ 1 investigator's brochure, briefing document, or other scientific advice document or response to agency questions.
- At least 5 years of interacting directly with clients, coordinating study teams and leading meetings relating to medical writing deliverables.
- ≥ 5 years of experience managing and mentoring writers.
- An ability to manage several parallel projects and (sometimes) demanding timelines.
- At ease with and experience of working with multiple accounts and document management systems and software.

What you will need:

- Higher level degree (Bachelor's/Masters) in a science or language discipline.
- An eye for detail yet an ability to let go of perfection.
- Impeccable written and spoken English.
- Understanding of and adaptability to different personalities and cultures.
- Ability to accept different learning styles, including learning through mistakes.
- At ease with communicating internally and with multiple-stakeholder client teams.

What you will do:

- Prepare a variety of regulatory documents and some medical communications documents, acting as lead medical writer, interacting directly with client teams.
- Ensure the smooth running of a project, including understanding and managing project scope, timelines and the impact of any changes or new requests.
- Advise client teams regarding the medical writing content of documents, ensure compliance with SOPs and relevant local and national guidelines.

- Mentor less experienced writers, review their writing, and provide advice to help them grow and develop

Career Progression

The usual career progression is as follows:

Role Title	Expected Timeframe in Role
Associate Medical Writer	1-2 years
Medical Writer	2-4 years
Senior Medical Writer	2-4 years
Principal Medical Writer	2+

If you are interested in this position, please complete the form on the recruitment page.