Senior Manager
Medical Writing

If you are looking for a position in a dynamic company where you can lead a team of medical writers working on projects that make tangible differences in the lives of patients with rare diseases, keep reading.

Role

We are seeking a highly experienced **Senior Manager in Medical Writing,** to lead our team in delivering regulatory documents of the highest standards. The ideal candidate will have extensive expertise in medical writing for regulatory submissions, proven leadership in mentoring and line management, and specialised experience in rare diseases and orphan drug development.

Azur's Mission

At Azur Health Science, we are not only specialists – we are advocates. Historically, rare disease has been overlooked, often seen as too complex or unprofitable to address. Today we see incredible progress, but there is still much more to do.

Our mission is to be a part of the progress by dedicating our expertise to this field, we aim to accelerate access to life-changing treatments for patients who have waited too long. Every rare disease deserves attention. Every patient deserves hope.

We are dedicated to delivering accurate, clear, and compliant documents that support our customers in achieving regulatory success.

Key Responsibilities

- **Team Leadership & Management**
  - Provide line management for a team of medical writers, including performance reviews, career development, and resource allocation.
  - Mentor and coach medical writers to enhance technical and professional skills.
  - Foster a collaborative, high-performance team culture.

- **Project Oversight & Quality Assurance**
  - Function as lead writer on large submission projects and other strategic writing projects.
  - Oversee the planning, development, and delivery of regulatory documents, and other submission-related documents, as necessary.

- Ensure compliance with regulatory guidelines (ICH, EMA, FDA) and internal quality standards.
- Serve as a senior reviewer and quality gatekeeper for key deliverables.

- **Strategic & Customer-Facing Responsibilities**
  - Function as a senior point of contact for customers, providing strategic guidance on regulatory writing projects.
  - Support business development activities, including proposal development and presentations.
  - Contribute to the external facing side of Azur Health Science by deepening your knowledge on rare diseases, writing articles or white papers for publication, and participating in team events to engage with the rare disease community.

Qualifications & Experience

- **Experience:**
  - **Minimum 10 years of experience** in regulatory medical writing, actively writing documents.
  - **At least 5 years of interacting directly with customers**, coordinating study teams and leading meetings relating to medical writing deliverables, ideally in an agency environment.
  - **At least 3 years of experience in line management or leadership roles** within a medical writing team.
  - Actively worked on ≥ 4 FDA or EMA submissions for marketing authorisation, ≥ 10 protocols, ≥ 10 CSRs, and ≥ 10 investigator's brochures, briefing document, orphan drug designation/maintenance report or other scientific advice document, or response to agency questions.
  - An ability to manage several parallel projects under demanding timelines.
  - At ease with and experience of working with multiple accounts and document management systems and software.
  - Demonstrated expertise in rare diseases and/or orphan drug development.
  - In-depth knowledge of global regulatory requirements and submission processes.

- **Qualifications:**
  - Ideally, a higher level degree (Bachelor's/Masters) in a science or language discipline.
  - An eye for detail yet an understanding of the balance between high quality and 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 customer teams.

- **Skills & Attributes:**
  - Ability to manage multiple complex projects under tight timelines.
  - Strong leadership and interpersonal skills with the ability to motivate and inspire teams.
  - Excellent written and verbal communication skills with meticulous attention to detail.
  - Demonstration of providing solutions and showing initiative in challenging situations.
  - Strong listening skills and emotional intelligence to foster effective collaboration.
  - High adaptability in dynamic environments and openness to change.
  - Proven experience in managing and supporting remote teams.

Why Join Azur?

- A rare opportunity to lead a highly skilled team in a dynamic, customer-focused environment.
- Work on impactful projects in rare disease and cutting-edge therapies.

Conditions

- **Location:** Mulhouse, France or Germany home or hybrid working
- **On-site presence:** required twice weekly during the initial onboarding month, followed by a minimum of four in-person meetings per year
- **Contract:** Full-time, CDI, cadre – forfait jours (FR), full-time permanent 40h/week (DE)
- **Start Date**: Flexible, ideally November 2025 but open until January 2026
- **Salary**: Starting gross annual salary at €60,000
- Competitive compensation and benefits package.

If you are interested in this position, please email your tailored CV and covering letter to recruitment@azurhealthscience.com.

For more information on how we handle your personal data during the recruitment process, please refer to our Recuitment Privacy Policy: https://azurhealthscience.com/recruitment-privacy-policy/.