Medical Writer

Industry	Biotechnology, Medical Devices
Discipline	Regulatory Affairs
Location	Tolland, CT (HQ) or Partial Home Office
Reports To	Project Manager, Medical Device & Regulatory

Nerac Analysts:
The Nerac Life Sciences/Medical Device Team works with medical device and biotechnology companies worldwide to support their regulatory approval/recertification and monitors the on-going safety and efficacy of their marketed products. The Medical Writer will be responsible for providing regulatory support during and after product regulatory approval, as an independent third-party reviewer of clinical and safety data.

In addition, the Medical Writer works with Nerac clients in an advisory capacity, building relationships that lead to Nerac becoming a trusted business advisor. The Analyst will be assigned target client accounts and be responsible for maintaining the client relationship and ensuring their continued satisfaction with Nerac. Support to clients ranges from completion of short opinion research reports to advisory projects, but may vary widely depending on client needs and the depth of the client relationship with Nerac.

Essential Requirements:

- Perform **Research** and provide **Analysis**
- Actively participate in **Advisory Services**
- Actively pursue **Professional Development**

Required Education/Experience/Characteristics:

- Undergraduate Degree or Advanced Degree in Biomedical or Medical sciences
- Strong technical expertise in Medical Writing, medical devices, CE Marks, Notified Bodies, or FDA/EU Medical Devices Directives
- Experience with ISO 13485 QMS and ISO 14971 Risk management preferred
- Experience creating Clinical Evaluation Reports for Medical Device submissions (US, EU, CFDA, Japan, Canada)
- Ability to review data and provide analysis in a clear and concise manner
- Advanced searching skills (Medline, Embase, PubMed, etc) highly desired but not required
- Good Client Service skills
- Medical Writer certification a plus
- Proven ability to work in a dynamic team environment essential

Must possess an education and background in *at least one* of the listed disciplines.

Also desirable:

- Knowledge of current government regulations and/or policies
- Demonstrated track record of industry thought-leadership through analysis of white papers, journal articles, blogs, and/or high profile speaking engagements
- Proficient public speaking skills including industry events, media and formal client presentation

- Strong analytical skills, both qualitative and quantitative
- Project Management skills and experience
- Deep intellectual curiosity about industry trends and emerging technologies
- Creativity/originality in finding the right solutions for clients
- Entrepreneurial, enthusiastic, collegial, and collaborative approach to work
- Exceptional organizational skills plus keep attention to detail and the ability to multitask
- Demonstrated ability to cultivate a network of valuable industry and academic contacts
- Ability to work with globally located team members
- Superior communication (speak, write, listen, presentation) skills
- Excellent Microsoft Office skills (Excel, PowerPoint, Access)
- Fluency in second language and international exposure a plus!

A writing sample will be required upon request.

For more information please go to:
https://www.nerac.com/career-opportunities/

To contact us directly:
careers@nerac.com