



Regulatory Analyst/Writer (Medical Device)

Industry	Medical Devices
Discipline	Regulatory Affairs
Location	Remote - Home Office
Reports To	Senior Analyst/Medical Writer

Nerac Analysts:

The Nerac Life Sciences/Medical Device Team works with medical device companies worldwide to support their regulatory approval/recertification and monitors the on-going safety and efficacy of their marketed products. The Regulatory Analyst/Writer will be responsible for providing regulatory support during and after product regulatory approval.

Key Responsibilities:

- Perform literature research and provide analysis
- Review device documentation and draft reports
- Communicate with clients in a professional manner
- Actively pursue continual learning and job-related development

Required Education/Experience/Characteristics:

- Undergraduate or advanced degree in biomedical or health sciences
- Demonstrated scientific or clinical writing skills
- Ability to review data and provide analysis in a clear and concise manner
- Advanced searching skills (Embase, PubMed, etc.)
- Experience reading, writing, and/or analyzing clinical or scientific literature
- Proven ability to multitask and adhere to timelines
- Proven ability to work in a dynamic team environment
- Excellent Microsoft Office skills (Word, Excel, Outlook)

Preferred Skills and Knowledge:

- Experience creating Clinical Evaluation or Literature Reports for Medical Device submissions (US, EU, China, Japan, Canada)
- Knowledge of medical device regulations and guidance
- Strong analytical skills, both qualitative and quantitative
- Good client service skills
- Medical writing 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 keen attention to detail
- Ability to work with globally located team members

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