JOB POSTING

Medical (Clinical) Writer

Primary Responsibilities and Duties:
Salamandra LLC (Salamandra) is a consulting firm located in Bethesda, Maryland that provides technical, strategic, and regulatory guidance to our clients, pharmaceutical companies. Salamandra is currently seeking a full-time Medical (Clinical) Writer to support their clinical practice area. This person will be responsible for preparing and reviewing clinical/scientific and regulatory documents in a fast-paced and multi-disciplinary team environment. Specific responsibilities of this position include, but are not limited to:

- Preparing and reviewing clinical/scientific documents for drug, biologic, and combination products for human use across a range of therapeutic indications and phases of clinical development. Document types include, but are not limited to:
    - Clinical pharmacology, safety, and efficacy sections of regulatory submissions (e.g., integrated summaries, Module 2 summaries, prescribing information, and risk management plans).
    - Clinical study documents (e.g., protocols, study reports, investigator brochures, and informed consent forms).
    - Other clinical, regulatory and scientific documents including special designation applications and requests, manuscripts, white papers, etc.
- Contributing to nonclinical and clinical data analysis and study result interpretation, including synthesis of large amounts of data and identification of potential issues.
- Collaborating cross-functionally with other organizational practice areas (e.g., CMC, nonclinical).
- Coordinating and communicating with project managers regarding technical issues, timelines, deliverables, etc.
- Communicating and coordinating with clients and contract research organizations, which may include questions or concerns regarding format, content, and status of data or reports.
- Suggesting or identifying changes, modifications, and improvements to the document preparation processes and templates to improve quality, efficiency and productivity.
- Providing QC review support as needed.
- Leveraging opportunities to promote Salamandra's services to new and existing clients.

Success Factors
Successful performance in this role is predicated on the ability to:

- Communicate, orally and in writing, in a clear, succinct, and organized manner that is appropriate for the audience.
- Think quickly and creatively in fast-paced, high pressure situations and provide thoughtful, measured responses appropriate for the audience.
- Adapt behavior/shift priorities in response to new information, changing conditions, or unforeseen obstacles.
- Analyze information, use sound judgment, and research precedents to generate/evaluate proposed and alternative approaches, draw logical conclusions, and make recommendations.
- Be thorough and conscientious to ensure work product/information is complete, accurate, and of the highest possible quality.

- Understand time requirements, as well as manage and meet agreed upon, and sometimes competing, deadlines by prioritizing and balancing own workload.
- Have great attention to detail and produce accurate work, even when under pressure.
- Have good listening skills.
- Work both independently as well as collaboratively across all levels of the organization in an engaged, matrixed leadership environment to achieve common goals and positive results.

Minimum Qualifications

- Bachelor's degree or an advanced degree (M.S., Pharm.D., Ph.D.) from an accredited institution in the life sciences or a health-related field.
- A minimum of 5 years medical writing experience in the pharmaceutical industry.
- Strong working knowledge of scientific terminology as well as medical, pharmaceutical and research concepts.
- Strong working knowledge of clinical research, the drug development process, and applicable US and ICH regulatory guidelines and documentation.
- Experience authoring regulatory submission documents and complex medical writing projects, including Integrated Safety Summaries / Integrated Efficacy Summaries, prescribing information, and risk management plans.
- Proficiency in Microsoft Office is required.
- Eligible to work in the U.S. without time limitations.

Candidates may forward their resume to hiring2123@salamandra.net.
(A Cover Letter is REQUIRED for consideration.)

Salamandra, LLC is proud to be an Equal Employment Opportunity employer. We celebrate the diversity of our employees and all employment decisions are made based on qualifications, merit, and business need. We offer competitive salaries and benefits, including: Paid Time Off (Holiday, Vacation, & Sick); 100% paid individual health care; retirement and flexible spending account plans; and a pleasant, professional office in downtown Bethesda, Maryland (Metro accessible), in addition to a flexible telecommuting policy.

Further information about the company can be found at http://www.salamandra.net.