JOB POSTING

Research Associate

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's Research Associate will support our regulatory consulting efforts across multiple disciplines (e.g., Clinical, Nonclinical, Chemistry Manufacturing and Controls (CMC), etc.). This person will be responsible for gathering, organizing, and summarizing relevant information/data that can be used to support clients through the various phases of drug development. Working closely with a team of regulatory and scientific experts, this person will ensure solutions are comprehensive and tailored to each client's unique needs. Specific responsibilities of this position include, but are not limited to:

- Supporting senior staff across relevant practice areas in the development of regulatory strategy and guidance to ensure that development activities are effective, and that regulatory documentation is accurate and compliant with relevant regulations, guidelines, and industry standards.
- Supporting senior staff in research and analysis by conducting literature searches, reviewing publications, researching regulatory/scientific precedent, and preparing summaries of findings.
- Reviewing regulations and guidance documents concerning various topics and summarizing how the findings are applicable or not applicable to a given product or situation.
- Preparing written or tabular summaries of data from publications or study reports to be included in technical documents for submission to regulatory authorities.
- Assisting in the organization, compilation, and electronic production of regulatory submissions and correspondences.
- Conducting comprehensive and formalized reviews of prepared documents to ensure accuracy and completeness of information against original source reports.
- Tracking deliverables against project timelines to ensure that submission deadlines are met and proactively identifying/communicating anticipated issues and/or deviations from project delivery schedules to senior staff and project managers (PMs) and suggesting appropriate strategies to mitigate risks.
- Delegating work to junior staff and monitoring progress through task completion, as appropriate (e.g., assign summaries, literature searches, general research, quality control evaluations (QCE), etc.).
- Maintaining current knowledge of existing and emerging regulations, standards, or guidance documents and communicate with senior/PM staff to ensure relevant rules or rule changes are incorporated into Salamandra policies and procedures.
- Demonstrating complete understanding of the organization's services/offerings and leveraging opportunities to market and sell products/services to new and existing clients.

Success Factors
Successful performance in this role requires the ideal candidate to be:

- Able to quickly learn new skills and proactively ask questions while working on deliverables with minimal supervision.
- Able to communicate clearly and effectively, orally and in writing, to different types of audiences, with a strong command of English grammar, usage, and writing conventions.
- Able to think quickly and creatively in fast-paced, high pressure situations and provide thoughtful, measured responses appropriate for the audience.

- Able to analyze information to draw logical conclusions and to apply multiple perspectives to facilitate complex problem-solving.
- Able to adapt behavior or work methods or shift priorities in response to new information, changing conditions, or unexpected obstacles.
- Exceptionally detail-oriented and able to be thorough and conscientious when performing work to ensure the information is complete, accurate, and of the highest possible quality prior to submitting for peer review, quality assurance checks, and client delivery.
- Self-motivated and continually seeking ways to enhance contribution to the team.

Minimum Qualifications

- Bachelor's degree required, preferably in the life sciences, chemistry, engineering, or health-related field.
- A minimum of 3 years of experience as a scientific/regulatory professional; fewer years of experience may be considered with a master's degree in a scientific or regulatory discipline.
- Strong knowledge of US regulatory standards related to pharmaceutical development and applicable guidance documents; knowledge of international regulatory environments/authorities is a plus.
- Strong communication, interpersonal and organizational skills are necessary to facilitate working in a small-group technical environment.
- Able to work both independently as well as collaboratively across all levels of the organization in a fast-paced, matrixed leadership environment to create high quality written reports and summary documents for use in regulatory submissions.
- Able to manage and meet agreed upon, and sometimes competing, deadlines by prioritizing and balancing own workload.
- In-depth familiarity with the advanced features of the Microsoft Office applications suite and Adobe Acrobat is expected.
- Authorization to work in the US without time limitations.

Candidates may forward their resume to hiring2126@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.