

JOB POSTING

Research Assistant

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 Assistant** 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 our 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 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 (akin to a "fact check") to ensure accuracy and completeness of information against original source reports.

*Note - This is **NOT** a laboratory position.*

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 moderate supervision.
- Exceptionally detail-oriented, as accuracy is essential.
- 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 analyze information to draw logical conclusions and to apply multiple perspectives to facilitate complex problem-solving.
- Self-motivated and continually seeking ways to enhance contribution to the team.

Successful Research Assistants will have the option to follow technical and/or management growth tracks and have access to company-sponsored training and coaching to advance technical skills, industry knowledge and professional competencies.

Minimum Qualifications

- Bachelor's degree required, preferably in the life sciences, chemistry, engineering, or health-related field. Related drug development and/or regulatory experience is a plus.
- Strong communication, interpersonal and organizational skills are necessary to facilitate working in a small-group technical environment.

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- Prior experience reviewing scientific literature, writing scientific documents, and organizing and analyzing data is highly valued.
- 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 hiring2125@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>.