

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 work with a team of regulatory and scientific experts to gather, organize, and summarize relevant information/data that can be used to support our clients as they navigate various phases and challenges of drug development. The Research Assistant also plays a key role in upholding Salamandra's quality system and will work to ensure that our solutions and deliverables are accurate and comprehensive. *Note - This is **NOT** a laboratory position.*

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.
- Conducting comprehensive and formalized reviews of prepared documents (akin to a "fact check") to ensure accuracy and completeness of information against original source reports.
- 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.
- Upholding/adhering to Salamandra's quality standards; supporting/participating in, as needed, Quality System-related activities.
- Supporting business development activities (e.g., researching information for scopes of work, proposals, or similar engagements), as needed.

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.

Research Assistants will have access to company-sponsored training and mentoring 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.
- 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.

About Salamandra, LLC

Our professional team is our greatest asset. 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: a generous Paid Time Off policy; 100% paid individual health care coverage; retirement and flexible spending account plans, a spacious, professional office in downtown Bethesda, Maryland (Metro accessible), and a flexible remote work policy. Salamandra is proud to be an Equal Employment Opportunity employer.

TO APPLY:

Candidates can forward their resume to [hiring2150@salamandra.net](mailto: hiring2150@salamandra.net).

A Cover Letter is REQUIRED for consideration.