Research Assistant

Primary Responsibilities and Duties
Salamandra LLC, a regulatory consulting company, is currently seeking a full-time entry-level Research Assistant to support our regulatory consulting efforts across multiple practice areas (e.g., Clinical, Nonclinical, Chemistry Manufacturing and Controls (CMC), etc.). This person will be responsible for gathering, organizing, and summarizing relevant data that can be used to support clients through the various phases of drug development. Working closely with a multi-disciplinary team, 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 precedent, and preparing summaries of findings
- Researching regulations and guidance documents concerning a particular topic and summarizing the findings
- 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 Quality Control Evaluations (QCE) of prepared documents to ensure accuracy and completeness of information

It should be noted that this is not a laboratory position nor is there a laboratory on site.

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 many 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

Job Qualifications:

- Bachelor's degree, preferably in the life sciences, chemistry, engineering, or health-related field is required. 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 with reviewing scientific literature, writing scientific documents, and organizing and analyzing data would be highly valued
- In-depth familiarity with the advanced features of the Microsoft Office applications suite is expected
- Authorization to work in the US without time limitations

Candidates may forward their resume to HR@Salamandra.net.
(Cover Letter REQUIRED for consideration.)

About Salamandra

Salamandra, LLC provides strategic, technical, and regulatory consulting services to the pharmaceutical industry for drug, biologic, and device development. Our primary products are strategic development advice and original writing of the scientific and regulatory documents that form the basis of a submission to the FDA or other regulatory authorities. We bring our multidisciplinary team approach and our experience across a wide range of therapeutic areas to clients from all around the US and the globe.

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 HMO; retirement and flexible spending account plans, and a pleasant, professional office in downtown Bethesda, Maryland (Metro accessible).

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