Nonclinical Pharmacology/Toxicology Regulatory Consultant

Primary Responsibilities and Duties

Salamandra, a regulatory consulting company, is currently seeking a full-time Pharmacology/Toxicology Regulatory expert to support their Nonclinical practice area. This person will be responsible for leveraging their scientific and regulatory nonclinical pharmacology and toxicology expertise to support clients through the various phases of drug development while working closely with a multi-disciplinary development team to ensure solutions are comprehensive and tailored to each client's unique needs. Specific responsibilities of this position include, but are not limited to:

- Providing support and advice to clients on the design, interpretation, and associated risks of nonclinical studies (e.g., pharmacology; toxicology; absorption, distribution, metabolism, and excretion [ADME]; toxicokinetics (TK); and safety) and on Good Laboratory Practice (GLP) requirements for programs as needed.
- Serving as a subject matter expert supporting development strategies and identifying strategic resolutions to issues identified during drug development regarding nonclinical pharmacology and toxicology studies.
- Preparing as primary author, reviewing, and providing regulatory input to nonclinical pharmacology/toxicology portions of relevant regulatory documents (IND, NDA, BLA, MAA, Meeting Briefing Packages, IB, annual reports, etc.) for drugs or biologics or other technical reports (e.g., white papers, memos, literature reviews).
- Advising clients on and/or providing interpretation of relevant regulatory requirements (e.g., for FDA, Health Canada, EMA, etc.).
- Collaborating cross-functionally with other organizational practice areas (e.g., CMC, clinical); communicating with clients and project managers regarding technical issues, timelines, deliverables, etc.
- Providing training and mentorship to internal staff, clients, and external vendors as needed.
- Identifying opportunities to market and sell 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; anticipate client needs and develop strategies and/or recommendations to address them;
- Analyze information, use sound judgment, and research precedents to generate/evaluate proposed and alternative approaches, draw logical conclusions, and make recommendations;
- Adapt behavior/shift priorities in response to new information, changing conditions, or unforeseen obstacles;

- Be thorough and conscientious to ensure work product/information is complete, accurate, and of the highest possible quality; and
- 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

- Ph.D. in Pharmacology and Toxicology, Pharmaceutical Sciences, or closely related discipline (applicable experience will be considered).
- Minimum of 5 years pharmaceutical industry or FDA experience in designing, analyzing, interpreting, and reporting nonclinical pharmacology and toxicology studies.
- Knowledge of regulatory guidelines and requirements and experience with nonclinical pharmacology/toxicology strategy development, study design, data interpretation, and risk assessment.
- Experience with the preparation of regulatory documents (e.g., IBs, Briefing Packages, INDs, CTAs, NDAs, and MAAs) in eCTD format.
- Experience interacting with the FDA on INDs, NDAs, and development programs; interaction with other regulatory authorities (e.g., EMA, Health Canada, etc.) is a plus.
- Knowledge of contract laboratory function and ability to interact with CROs/laboratories to direct programs is a plus.
- Proficiency in Microsoft Office is required.
- Eligible to work in the U.S. 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.