JOB POSTING

Clinical Pharmacology Regulatory Consultant

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 Clinical Pharmacology Regulatory Consultant will support our Clinical practice area. This person will be responsible for leveraging their scientific and regulatory clinical pharmacology expertise to support our 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 clinical pharmacology studies (e.g., pharmacokinetics [PK]; pharmacology; absorption, distribution, metabolism, and excretion [ADME]; drug-drug interactions [DDI]; and pharmacodynamics [PD]) and the implications of results.
- Advising clients on and/or providing interpretation of relevant regulatory requirements (e.g., FDA, Health Canada, EMA, etc.) to support the development of drugs and biologics, and providing regulatory input for submissions (e.g., IND, CTA, NDA, BLA, MAA, etc.).
- Preparing, as primary author, or reviewing clinical pharmacology portions of all relevant regulatory documents (e.g., IND, CTA, NDA, BLA, MAA, Meeting Briefing Packages, IB, annual reports, etc.).
- Planning and managing clinical pharmacology studies including: study design; development and review/writing of study protocols; identification and assessment of potential Contract Research Organizations (CROs) and bioanalytical laboratories; communication with CROs to facilitate study conduct; review of data management and statistical analysis plans; and review/writing of clinical study reports (CSRs).
- Researching, gathering, and integrating data from published literature, relevant databases, and/or external subject matter experts to support development strategy or to identify strategic resolutions to issues identified during drug development.
- Collaborating and working cross-functionally with the CMC, nonclinical and other clinical practice areas across the organization.
- Serving as subject matter expert regarding clinical pharmacology related matters on behalf of clients including: responding to questions from regulators; participating in teleconferences; attending face-to-face meetings; giving oral and written summaries and explanations; and other duties as assigned.
- Overseeing project progression by communicating with clients regarding technical issues, timelines, deliverables, etc., and elevate issues to project managers as needed.
- Providing training and mentorship to internal staff, clients, and external vendors as needed.
- Identifying opportunities to market and sell products/services to new and existing clients.

Success Factors
Successful performance in this role is predicated on the ability to:

- Communicate effectively, orally and in writing, in a clear, succinct, and organized manner that is appropriate for the audience, whether to clients, leadership, the organization or individual team members.
- Write clear and concise study results, interpretations, and summaries for reports and regulatory documents.
- Think quickly and creatively in fast-paced, high pressure situations and provide thoughtful, measured responses appropriate for the audience.

- Adapt behavior or work methods and shift priorities in response to new information, changing conditions, or unexpected obstacles.
- Analyze information, use sound judgment, and research precedents to generate and evaluate alternative approaches, draw logical conclusions or inferences, and make recommendations.
- 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.
- Anticipate client needs and develop strategies and/or recommendations to address them.
- Work both independently as well as collaboratively across all levels of the organization in a diverse, matrixed leadership environment to achieve common goals and positive results.
- Effectively lead tasks or projects by planning, delegating, coordinating, monitoring, and providing feedback on the work assignments of others, as appropriate.
- Coach others on how to perform tasks and develop their capabilities within the standards of the organization using formal or informal methods.

Minimum Qualifications

- PharmD or Ph.D. in Pharmacokinetics, Pharmacology, Pharmacy, Pharmaceutical sciences, or closely related discipline (an M.S. in a relevant science in combination with applicable experience may be considered).
- Minimum of 8 years pharmaceutical industry or FDA experience in designing, analyzing, interpreting, and reporting clinical pharmacology studies.
- Previous FDA experience or other relevant regulatory experience is a plus.
- Experience with the preparation of regulatory documents (e.g., IBs, Briefing Packages, INDs, CTAs, NDAs, and MAAs) in eCTD format.
- Expertise in the areas of clinical pharmacology, PK/PD, pharmaceutical development, translational principles, and other relevant scientific disciplines (e.g., ADME).
- Knowledge of regulatory guidelines and requirements, and experience with clinical pharmacology strategy development, study design, data interpretation, and risk assessment.
- Knowledge of contract bioanalytical laboratory function and ability to interact with CROs/laboratories to direct programs.
- 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.
- Proficiency in Microsoft Office is required; population PK and/or PBPK modeling/analysis is a plus.
- Eligible to work in the U.S. without time limitations.

Candidates may forward their resume to hiring2121@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.