JOB POSTING

Senior Biologics 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 is currently seeking a **Senior Biologics Regulatory Consultant** with strong regulatory or technical writing experience in biologics (e.g., blood products, recombinant therapeutic proteins, monoclonal antibodies, cell and gene therapies, vaccines, or biosimilars, etc.) to support and grow our Biologics practice area. We are looking for a self-sufficient, experienced leader with a passion for growth who can help expand our biological drug product client base while enjoying a stimulating learning environment. This person will be responsible for leveraging their scientific and regulatory biologics expertise to support clients through the various phases of biologics/biosimilar-based pharmaceutical, nonclinical and clinical 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:

- Serving as a Regulatory Lead and subject matter expert (SME) for the Biologics practice area.
- Advising clients on and/or providing interpretation of relevant regulatory requirements (e.g., FDA, Health Canada, EMA, etc.) to support biologics development including strong emphasis on providing input for CMC development activities.
- Preparing, as primary author, or reviewing relevant portions of regulatory documents related to regulatory submissions (BLA, IND, NDA, MAA, Meeting Briefing Packages, IB, annual reports, etc.).
- Providing support and advice to clients on product quality expectations as relevant to the stage of development and eventual commercial presentation.
- Reviewing and assessing source documentation, testing procedures/methods, facilities, raw materials from suppliers, vetting pharmaceutical/contract research organization (CRO) partners and/or any other companies to ensure they align with regulatory requirements.
- Collaborating and working cross-functionally with the nonclinical, clinical, and other CMC practice areas across the organization.
- Providing training and mentorship to internal staff, clients, and external vendors as needed.
- Identifying and supporting growth opportunities to expand and market services to existing and new 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; superior ability to write clear and concise regulatory reports, summaries and 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 or 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 fast-paced, matrixed leadership environment to achieve common goals and positive results.
- Effectively lead a project team by planning, delegating, coordinating, monitoring, and providing feedback on the work assignments of others.
- Coach others on how to perform tasks and develop their capabilities within the standards of the organization using formal or informal methods.
- Be quality-focused with a growth-oriented mind-set and passion for learning.

Minimum Qualifications

- Minimum of 10 years pharmaceutical industry or FDA experience in the regulation of biologics; consulting experience strongly preferred.
- Ph.D. in biology, chemistry, biochemistry, or closely related discipline (an M.S. in a relevant science in combination with applicable experience may be considered).
- Expertise in CMC and Quality requirements and strategy throughout product lifecycle, including biologics/biosimilar development and post-approval; experience also with small molecule drugs a plus.
- Comprehensive understanding of CMC biologics regulatory (e.g., FDA, ICH, EMA) requirements and relevant GMP regulations and experience with the preparation of regulatory documents in eCTD format.
- Experience with CMC data interpretation and risk assessment.
- Knowledge of contract manufacturer function and ability to interact with CMOs/laboratories to guide programs.
- Experience interacting with the FDA on biological/biosimilar product development programs. Interaction with international regulatory authorities (e.g., EMA, Health Canada, etc.) is a plus.
- Experience with device regulations, combination products and/or small molecules 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 hiring2127@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.