JOB POSTING

Chemistry, Manufacturing, and Controls (CMC) 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 **CMC Regulatory Consultant** will support our CMC practice area. This person will be responsible for leveraging their scientific and regulatory CMC 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:

- 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 CMC development activities.
- Preparing, as primary author, or reviewing CMC portions of all relevant regulatory documents (IND, NDA, BLA, MAA, Meeting Briefing Packages, IB, annual reports, etc.).
- Providing support and advice to clients on drug substance and drug product quality expectations as relevant to the stage of development and eventual commercial presentation (e.g., researching, gathering, and integrating data to identify strategic resolutions to issues identified during drug development.).
- Reviewing and assessing source documentation, methods, facilities, raw materials from laboratories, pharmaceutical/contract research organization (CRO) partners, and any other companies to ensure they align with regulatory requirements.
- Collaborating and working cross-functionally with the nonclinical and clinical practice areas across the organization.
- Serving as subject matter expert regarding CMC related matters on behalf of clients including: responding to questions from regulators; participating in teleconferences; attending face-to-face meetings; giving oral 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.
- 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 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.

Minimum Qualifications

- Minimum of 8 years pharmaceutical industry or FDA experience in CMC and quality practice areas; consulting experience strongly preferred.
- Ph.D. in 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 the product lifecycle, including drug development and post-approval.
- Experience with the preparation of regulatory documents (e.g., IBs, Briefing Packages, INDs, CTAs, NDAs, and MAAs) in CTD format.
- Experience with CMC strategy, 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 INDs, NDAs, and development programs. Interaction with other regulatory authorities (e.g., EMA, Health Canada, etc.) is a plus.
- A comprehensive understanding of CMC regulatory (e.g., FDA, ICH, EMA) requirements, guidelines, and relevant government regulations as they apply to the pharmaceutical development, acceptance of investigational products, approval of registration and post-approval changes to marketed products.
- Experience with device regulations, combination products and/or biologics 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 hiring2122@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.