Scientist I – Pharmaceutical Development

An opportunity exists for an exceptional individual in the area of pharmaceutical development. Wolfe Laboratories conducts rational formulation development that leverages a molecular understanding of the pharmaceutical and biopharmaceutical attributes for the delivery of drugs, including poorly soluble drugs, via conventional and non-conventional oral formulations as well as complex parenterals.

The successful applicant will be a key member of the team and will be responsible for understanding characteristics of candidate drugs and developing and executing the formulation approach that will be most successful. Furthermore, the successful candidate will define performance criteria for any products developed to ensure that clinical performance of manufactured product is acceptable. The company utilizes a wide range of *in vitro* (both biology and physical/analytical chemistry based), *in situ*, and *in vivo* techniques to achieve this goal. Creativity and innovation, built on sound technical knowledge and excellent problem-solving skills, are required in order to meet the challenges posed.

**DUTIES AND RESPONSIBILITIES:**

**Scientific Responsibilities:**

- Plan, design, coordinate, set priorities, and at times, lead teams to manage programs of work to achieve project targets in a timely fashion and to agreed quality standards by applying technical knowledge and expertise.
- Aid and influence the selection of formulations from a product design perspective.
- Manage programs of experimental work and predictions to characterize and understand the pharmaceutical properties (physicochemical and biopharmaceutical) of drug substances and formulations.
- Implement and/or lead project work and other improvement activities.
- Evaluate physicochemical properties of small molecules relevant to drug development and subsequently communicate the interpretation and implication of results to clients.
- Develop analytical methods and characterize product variants.
- Execute and oversee specialized analytical testing and generation of technical documents.
- Maintain a strong awareness of current scientific literature, particularly in the area of drug substance and drug product characterization, and actively apply new concepts as appropriate.
- Design experiments to develop pre-clinical and clinical formulations of drug candidates to support drug discovery and development.
- Design experiments to determine the stability in prototype clinical formulations, to detect and identify the decomposition products, and to achieve formulations with acceptable shelf-life.
- Perform laboratory experiments related to the above.
- Assess and report data with a clear understanding of its reliability, interpret findings, and draw authoritative conclusions and recommendations so that their significance can be appreciated.
- Apply technical knowledge to the company improvement projects and the evaluation of new technology/processes. Collaborate with specialist scientific and/or technology teams.
• May supervise co-workers and contribute to their training and development by acting as coach/mentor, giving immediate feedback, as appropriate. Develop personal performance by actively seeking feedback and support from peers.
• Will present information for discussion at project teams. Will be expected to influence colleagues in other areas/functions and/or in external groups.
• Will work as a member of cross-functional teams, with a large degree of independence representing own area of expertise.

Client Interaction Responsibilities:
• Interface with clients to develop an in depth understanding of client objectives and define solutions to meet their program requirements.
• Develop compelling approaches and solutions to address client needs.
• Engage clients in development of solutions by applying a broader perspective.
• Write persuasive proposals for the projects.
• Regularly interact with clients to keep them abreast of project progress.
• Write and review interim and final reports.

REQUIRED BACKGROUND AND EXPERIENCE:

• Ph.D. in pharmaceutical chemistry, organic chemistry, biochemistry, chemical engineering or closely related discipline.
• Two or more years of experience in drug development from the post discovery phase to the initial clinical trials phase.
• In depth expertise in biopharmaceutics.
• Expertise in the field of physicochemical analysis and structural characterization.
• Hands-on experience with method development as well as analytical methods used for physicochemical characterization of pharmaceutical products such as spectroscopy and HPLC analysis.
• A demonstrated drive to apply technical knowledge to developing drug delivery systems and formulations.
• Established track record of significant contributions as an individual technical expert as well as the ability to thrive in a multi-disciplinary team environment.
• Outstanding written and oral communication skills as well as polished and persuasive client presentation skills.
• Flexibility and outstanding time management skills to provide the full range of pharmaceutical support (including project representation) across many projects.

ADDITIONAL DESIRABLE BACKGROUND:

• In depth drug development expertise in two or more of the following formulation types: liquid, lyophilized, dispersed systems, solids, and/or semi-solids.
• Expertise in HPLC, LC/MS, DSC, TGA, and other analytical techniques.
• Ability to propose realistic reaction mechanisms for drug degradation prior to identification of actual decay products.
• Facility with computational chemistry tools to predict physical properties.
• Demonstrated capability with in silico pharmacokinetic models for predicting exposure following oral or parenteral administration.

Interested candidates are requested to email a copy of their resume with a cover letter, unofficial college transcripts, and salary requirements, to: steve.pangione@wolfelabs.com.

Wolfe Laboratories, Inc. (WLI), located in Woburn, MA, is a premier contract research organization that provides integrated early drug development solutions to the biopharmaceutical industry. Wolfe Laboratories is an essential element of the drug development ecosystem, recognized by global and virtual biopharmaceutical companies as a science-driven organization whose mission is to provide outstanding discovery and development services tailored to its clients’ needs for rational formulation development. Wolfe Laboratories integrates the critical path components of early development to ensure that programs advance while meeting rigorous scientific demands with flexibility to address dynamic challenges and aggressive timelines. Wolfe Laboratories’ vision is to improve human health, and we continue to strive towards that goal by embracing our core values of integrity, excellence and teamwork. The company has a high percentage of repeat clients, which is a testament to its long-term commitment of continual investment in its capabilities to meet biopharma’s growing demand for high quality, integrated early development services.

For more information visit us at: www.wolfelabs.com.

Wolfe Laboratories, Inc. is an Equal Employment Opportunity employer.