# Associate Scientist / Scientist (Small Molecule Product Development)

Wolfe Laboratories LLC., a subsidiary of Pace Analytical Life Sciences, is a premier Contract Research and Development Organization located in Woburn, MA, providing pharmaceutical development services for small molecules, biologics, oligonucleotide therapeutics, and other biopharmaceutical drug candidates.

We are currently seeking Scientists to support the rapid growth of our organization. As key members of the Pharmaceutical Development team these roles will require high-performing individuals who can design and execute studies supporting the pharmaceutical development of small molecule drugs. We are looking for individuals with a solid understanding of the analysis and/or formulation of pharmaceutical products as well a good working knowledge of the drug development process. These positions are critical in the operations of the organization and for the management of client drug development projects.

## DUTIES AND RESPONSIBILITIES:

**An ideal candidate would specialize and possess the skills to work in one or more of the following areas:**

**Analytical Chemistry:**

- Develop methods to characterize and understand the pharmaceutical properties (physicochemical and biopharmaceutical) of drug substances and formulations.
- In-depth understanding of HPLC and other chromatographic separations including the ability develop separation methodologies and understanding of method validation following FDA/ICH guidance
- Understanding of physical characterization of small molecule drugs, including particle size analysis, DSC, TGA and XRPD.
- Experience in a variety of other analytical and spectroscopic techniques including Karl Fischer titration, UV-Vis, IR/NIR, fluorescence, capillary electrophoresis, and dissolution
- Working knowledge of mass spectroscopy including TOF and LC-MS is a plus

**Formulation Development:**

- Design and conduct pre-formulation and formulation studies for the development of efficacious and stable parenteral, solid oral, ophthalmic, and other dosage forms
- Understanding of drug degradation processes and formulation approaches to prevent product degradation
- Experience with formulation processes including milling, preparation of solutions/suspensions, spray drying, lyophilization, tableting/coating, and capsule filling.

**General Responsibilities:**

- Will work as a member of cross-functional teams, with a large degree of independence representing own area of expertise. Execute and oversee

specialized analytical testing and generation of technical documents. 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.

- Interface with clients to develop an in depth understanding of client objectives and define solutions to meet their program requirements by writing persuasive proposals for the projects. Regularly interact with clients to keep them abreast of project progress. Will present information for discussion at project teams. Will be expected to influence colleagues/clients in other areas/functions and/or in external groups. Write and review interim and final reports.
- Maintain a strong awareness of FDA and other regulatory requirements in the area of pharmaceutical product development. Stay up to date with current scientific literature, particularly in the area of drug substance and drug product characterization, and actively apply new concepts as appropriate.
- Apply technical knowledge to the company improvement projects and the evaluation of new technology/processes. Collaborate with specialist scientific and/or technology teams.

**REQUIRED BACKGROUND AND EXPERIENCE:**

- Ph.D. in Pharmacy, pharmaceutics, pharmaceutical chemistry, organic chemistry, biochemistry, biophysics, chemical engineering or closely related discipline. Scientist-level candidates will require at least 2 years of post-doctoral or industrial experience.
- Understanding of drug development from the post discovery phase to the initial clinical trials phase.
- 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.

Pace Analytical is an Equal Opportunity Employer and will not discriminate against any applicant for employment on the basis of race, age, religion, sex, veterans, individuals with disabilities, sexual orientation, or gender identity.