Position Title: Development Engineer I
Department: Pharmaceutical Development

Overall Responsibility:
We are seeking a highly motivated, experienced scientist or engineer to join the Pharmaceutical Development group to provide technical leadership and hands-on performance in support of Pulmatrix development programs. This position will be a lead member of the Process Development group, which is responsible for developing engineered-particle production and filling processes at pilot and commercial scales. This position will work closely across functional areas on product development teams, as well as manage external contractors. The work is highly collaborative and requires excellent communication skills and the ability to be part of a team. The successful candidate must have pharmaceutical product development knowledge to contribute to our CMC strategy for novel pulmonary formulations, and have a proven ability to meet technology research and development goals within aggressive timelines. The ideal candidate will have expertise in process development of engineered particles and aerosols for pulmonary drug delivery.

Key Tasks and Responsibilities:

- Developing pharmaceutical manufacturing processes
- Provide key technical direction for specific aspects of drug product development
- Participate in multi-functional drug product development teams
- Design, conduct, evaluate and interpret scientific studies to drive the development and understanding of our dry powder technology platform and lead drug development programs
- Work closely and coordinate cross-functionally with formulation, solid-state, analytical and aerosol scientists and process engineers to develop robust formulations and processes in support of development projects
- Assist in the management and troubleshooting of manufacturing operations at contract sites, including directing product development studies and reviewing batch production records
- Author protocols, pharmaceutical development reports, SOPs, and other scientific/technical documents, which may support regulatory filings
- Present study results to Formulation and Process Development team and summaries to cross-functional project teams
- Participate in the development of the Pulmatrix intellectual property portfolio
- Maintain a comprehensive understanding and review of pertinent scientific literature and industry initiatives
- Possibility of managing daily activities of junior research associates and scientists or engineers to achieve team goals

Skills and Attributes:

- Command of physics, chemistry, and engineering principles
- Exceptional scientific, technical, and problem-solving skills with the ability to design experiments and interpret data independently

- Strong working knowledge of statistical analysis tools, in particular experimental design and interpretation of complex data sets
- Knowledge of process development for the production of pharmaceutical products
- Experience with process technology transfer to contract manufacturing organizations
- Excellent technical laboratory skills
- Reliable, self-motivated individual with positive attitude
- Team-oriented with ability to work with junior and senior staff
- Dedication to documentation and strong attention to detail
- Excellent oral and written communication skills, with the ability to prepare and present data to internal and external working teams
- Ability to effectively manage time and prioritize tasks to meet tight timelines and shifting priorities in a fast-paced environment
- Pharmaceutical cGMP manufacturing experience is a plus
- Experience with particle engineering for pharmaceuticals, especially pulmonary drug delivery and interpretation of aerosol, solid-state and chemical analyses is a plus
- Experience with pharmaceutical solids handling technology and processes, especially powder filling technology, is a plus
- Experience working across scales, and direct scale-up experience, is a plus
- Formal training in experimental statistics, and demonstrable competence in the scientific method, is a plus
- Desire for continued training and growth opportunities, including willingness to learn new skills and contribute outside of specific area of expertise

Position Requirements:
Minimum of a B.Sc. degree in Chemical Engineering and 6+ years of relevant industry experience in biotech/pharmaceutical R&D *OR* a M.Sc. in Chemical Engineering with 4+ years of relevant experience in biotech/pharmaceutical R&D. A combination of experience and education will be taken into consideration for position and title.

- Experience in process development and problem solving
- Thorough operational understanding of regulatory requirements and industry standards for development of high quality development programs, including quality by design principles and risk analysis tools
- Ability to work in a pilot lab and/or commercial facility that handles active pharmaceutical ingredients
- Will require domestic and international travel, up to 25% of time
- Must be authorized to work in the United States for any employer without the need for sponsorship

Contact: jobs@pulmatrix.com with cover letter and CV