Position Title: *Scientist III / Senior Scientist I*
Department: *Analytical Development*

At Pulmatrix, we are developing innovative inhaled therapies to address serious pulmonary diseases using our clinically validated, proprietary iSPERSE technology. iSPERSE is a dry powder technology developed, patented and validated by Pulmatrix scientists and engineers to improve how drugs are directed into the lungs. iSPERSE products are designed to maximize local drug concentrations and reduce systemic side effects, in order to make possible a new generation of inhaled therapies to improve patient outcomes.

Our pipeline of inhaled therapies represents innovative, first-in-class products. Our proprietary pipeline of novel therapies for respiratory diseases is led by PUR1900, PUR1800 and PUR5700. PUR1900 is an inhaled anti-infective to treat ABPA in severe asthmatics and cystic fibrosis patients. PUR1800 and PUR5700 are novel inhaled anti-inflammatory compounds that selectively inhibit kinases involved in inflammation.

Job description:
This role leads drug development programs for the Analytical Development group at Pulmatrix. The position requires expertise in laboratory techniques used for small molecules including HPLC/UPLC, KF, UV/Vis. The position requires expertise in inhaled product testing, including cascade impaction and delivered dose testing. Activities will include analytical method development, method transfer, method validation, and routine testing.

The position will work with more junior staff in the development and implementation of a range of analytical testing methods for the characterization of our solid-based inhalation dosage formulations. Additionally, the position will work with the Quality Control team to facilitate method transfer, validation, and testing at CRO(s).

The candidate is expected to support our CMC strategy for novel pulmonary formulations through contribution to the CMC project teams and have a proven ability to meet development goals within aggressive timelines. The work environment is highly collaborative, requires excellent communication skills and the ability to be part of a cross-functional product development team.

Key Responsibilities:
- Develop analytical methods to characterize critical quality attributes of drug substance / drug product intermediates and drug product
- Plan, execute and document method development, analyses and qualification assessment activities related to drug product development
- Document, compile, interpret, and audit data
- Lead aerosol testing
- Lead specifications development and justification of specifications
- Design and oversee stability studies
- Work with quality control to oversee contract research organization(s) performing method transfer, method validation, and stability testing
- Comply with safety guidelines and good laboratory practice which includes but is not limited to the maintenance of laboratory documentation, written procedures and laboratory notebooks
- Author, review, and approve documents for regulatory submissions

- Lead Analytical Development in cross-functional teams and projects
- Work with hazardous materials and chemicals in accordance with Pulmatrix safety policies and procedures
- Inspire and motivate others

Skills and Attributes:

- Expertise in chromatographic techniques (HPLC/UPLC/GC) including troubleshooting of equipment and methodology
- Proficiency in the use of wet chemistry and general analytical laboratory techniques
- Expertise in the development, assessment, and validation of analytical methods.
- Expertise in aerosol characterization
- Strong qualitative and quantitative data analysis and interpretation skills
- Understanding of GLP and GMP
- Experience supervising and providing guidance to junior scientist(s)
- Ability to work successfully independently and in a team environment
- Excellent written and verbal communication skills
- Established organizational skills
- Ability to work in a fast pace environment, manage priorities, and maintain timelines for multiple activities

Qualifications:

- Minimum of a BS/BA in Chemistry, Analytical Chemistry, Biochemistry or related field and 10 years of relevant industry experience in biotech/pharmaceutical R&D, MS with 6+ years or PhD with 3+ years of experience. A combination of experience and/or education will be taken into consideration for position and title.
- May require travel
- Must be authorized to work in the United States for any employer without the need for sponsorship