

PROCESS DEVELOPMENT SCIENTIST

BOSTON, MA | FULL-TIME

Cytovia Therapeutics is a biotechnology company that aims to accelerate patient access to transformational immunotherapies, addressing several of the most challenging unmet medical needs in cancer. Cytovia focuses on Natural Killer (NK) cell biology and is leveraging multiple advanced patented technologies, including an induced pluripotent stem cell (iPSC) platform for CAR (Chimeric Antigen Receptors) NK cell therapy, next-generation precision gene-editing to enhance targeting of NK cells, and NK engager multi-functional antibodies. Our initial product portfolio focuses on both hematological malignancies such as multiple myeloma and solid tumors including hepatocellular carcinoma and glioblastoma. The company is establishing R&D and GMP manufacturing operations in the greater Boston area and partners with Cellectis, CytoImmune, the Hebrew University of Jerusalem, INSERM, the New York Stem Cell Foundation, STC Biologics, and the University of California San Francisco (UCSF).

The Role:

The candidate will perform activities related to the development and implementation of analytical methods for the testing, lot release and characterization of Cytovia's innovative gene-modified cell-based therapeutic products. This individual will be responsible for developing and/or optimizing new and existing analytical methods (in-house, in the lab and outsourced) to facilitate the progression of Cytovia's product pipeline programs

Key Responsibilities:

- Work in the laboratory to develop and/or re-optimize new and existing analytical methods for the lot release and characterization of iPSC-derived gene-edited CAR NK products with specific cell-based potency assay development expertise.
- Routine operation of potency assays and other analytical methods to support characterization of iPSC-derived gene-edited CAR NK products as required.
- Oversee analytical method development and optimization with external partners as required.
- Execution, review and approval of method development reports, protocols and process documents as required.
- Assist in the preparation of CMC regulatory submissions.
- Assisting with comparability protocol design and execution as required
- Support CMO production activities as needed
- Other activities as may be assigned

Requirements:

- PhD in Biological Sciences, Bioengineering, Chemistry or an associated discipline or Master of Science in related discipline with additional industry experience
- Minimum of three years of experience in the biotechnology or pharma industry with a primary focus on the development of analytical methods for product development, characterization and lot release testing.
- Demonstrated experience of development and optimization of cell-based assays (e.g. FACS, HTRF, ELISA, Luminescence, etc) for lot release and characterization.
- Demonstrated experience of engineering cell lines to include (e.g.) vector construction, exogenous expression of cell surface receptor(s), single cell cloning, etc,
- Demonstrated experience of characterization and maintenance of transfected clonal cell lines.
- Knowledge of analytical method qualification and validation.
- Experience with the development and application of analytical techniques, including Capillary Electrophoresis, DNA sequencing, qPCR/PCR, ddPCR.
- Experience of the characterization and lot release testing of gene-edited cell-based products desirable.
- Sound understanding and demonstrated application of statistical methods/tools.
- Excellent interpersonal skills and outstanding organizational skills
- Excellent written and oral communication skills
- Creative problem solver
- Ability to operate in a fast-paced, multi-disciplinary industrial environment

Cytovia Therapeutics is an Equal Opportunity Employer

We strive to create a space free of both explicit and implicit discrimination and harassment where everyone feels safe, heard, and valued. The character of our employees is as important as their talent, and we're proud of the team and environment we're assembling as we grow.