MANAGER/ASSOCIATE DIRECTOR, QUALITY CONTROL

PUERTO RICO | 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 Manager/Associate Director, Quality Control is responsible for executing Quality Control Strategy at Cytovia's new GMP facility and will work closely with the analytical development team to establish and support standards for GxP compliance. The role of the Manager/AD is to provide operational leadership and will be responsible for the oversight of teams that are assigned to perform environmental monitoring and product release testing at the GMP Manufacturing facility in Aguadilla, PR. The manufacturing facility will include the entire product lifecycle; Cell banking, Drug Substance, Drug Product, and Pack/Label activities in an aseptic/sterile environment.

Key responsibilities

- Establish new QC laboratory and strategy for the company, including QC analytics for in-process controls, drug substance and drug product, as well as environmental monitoring program.
- Author, review and approve SOPs, Protocols, Reports relating to QC analytical processes, test methods and related equipment maintenance.
- Work with Analytical Development scientists to ensure development of robust and phase appropriate GMP state transferable assays into QC laboratories.
- Establish roadmap for the transition of analytical testing from early to late phase clinical and commercial readiness.
- Ensure QC staff are adequately trained in compliance with established procedures.
- Oversee all related QC activities such as but not limited to: Drug Product Release Testing, Stability Programs, and Environmental Monitoring.
- Write and review applicable CMC sections of regulatory filings for the submission of IND.
- Author GMP stability protocole and reports and ensure stability protocols are executed properly.

- Participated in clinical and commercial material release through generation of COAs and other related lot release documents.

- Ensure quality control activities conducted internally and with contracted services lead to robust methods for product testing and release.

- Experience managing cGMP laboratory operations in support of clinical and commercial manufacturing.

Requirement:

- Minimum of 10 years working in a biopharmaceutical, cellular therapy or gene therapy
- Demonstrated track record of compliance with current regulations, with direct experience in regulatory submissions for IND/BLA and other related product development activities
- Excellent technical writing, verbal and written communication skills
- Excellent collaboration, trouble shooting, and problem-solving skills
- Strong team player that can also work independently to achieve goals and objectives
- Strong computer skills with Word and Excel; experience with e-Systems is preferred
- Ability to work effectively in a fast-paced environment with cross functional departments, own multiple projects and meet the assigned timelines
- Expertise in analytical methodology for biological products, including knowledge of current trends
- Ability to develop a wide range of methodologies/technologies and perform advanced data analysis

What we offer:

- Competitive salary (DOE)
- 401(k) employer match, health, dental, vision benefits.
- Professional training and development opportunities.

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.