ASSOCIATE DIRECTOR/DIRECTOR, QUALITY ASSURANCE

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 Director, Quality Assurance is responsible for executing the Quality System at Cytovia's new GMP facility in Puerto Rico and will work closely with the development team to establish and support standards for GXP compliance. The manufacturing facility will include the entire product life cycle, including Cell banking, Drug substance, Drug product, and Pack/Label activities in an aseptic/sterile environment.

Key responsibilities:

- Play a key role in development of the Master Validation Plan and individual validation plans. Assist in the development of the overall validation strategy for Cytovia's new GMP facility.
- Provide GXP quality assurance (QA) support activities consistent with FDA, EU and ROW requirements to support Cytovia's cell therapy and biologic programs.
- Establish Cytovia's QA strategy and operational objectives.
- Represent the QA function in CMC meetings.
- Manage both the external vendor qualification program and internal audits. Conduct GMP vendor qualification audits and processes relating to clinical drug development.
- Responsible for managing deviations, investigations, change control and OOS processes.
- Responsible for approving master batch records and specification documents.
- Responsible for review of QC analytical method validation/qualification protocols, reports, test methods and GMP test results to assess suitability of product disposition.
- Coordinate and conduct batch record review and lot disposition (Cell Banks, API/DS, DP & Labeling/packaging).

- Be a resource as Cytovia voice of Quality for GMP requirements.
- Participate in inspection readiness preparation, corrective action responses.
- Ensure/establish QP declaration across programs and supply chain. Ensure chain of custody for shipment of product.
- Manage day to day emerging QA issues.

Requirement:

- BS and 10+ years of QA experience in the Life Science industry. MS preferred.
- Minimum of 5 years of QA auditing experience with outsourced cell therapy and/or biologics manufacturing vendors.
- Experience with cell therapy and/or biologic programs required.
- Proficient knowledge and direct experience with global GMP requirements.
- Must have excellent interpersonal, organizational, and communication skills as well as the ability to work effectively and independently as part of a multidisciplinary team.
- Must have close attention to detail and provide hands-on support for operational activities.

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.