SENIOR OPERATOR OF MANUFACTURING

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 candidates will be part of a Cell Therapy Manufacturing team and will be responsible for manufacturing of cellular therapy products for clinical applications. They will be responsible for following Current Good Manufacturing Practices (cGMPs) to carry out end-to-end processing and verification of patient-derived clinical cellular therapy products.

Key Responsibilities:

- Provide technical expertise to resolve manufacturing issues and interact with support groups to ensure production targets are met and product and process comply with cGMPs.
- Execution of manufacturing batch records, work instructions and/or SOPs, with minimal instruction on a day-to-day basis and a focus on proactive 'right the first time' executions.
- Assist with batch record reconciliation and timely documentation.
- Revise, author, and review GMP documentation
- Collaborates closely with Manager to ensure daily unit of operations are scheduled appropriately and communication across the manufacturing team is seamless and streamlined.
- Performance of all manufacturing activities in clean room (ISO 7) environment with specialized gowning.
- Execution of cell manufacturing and cell processing activities and maintaining aseptic technique during processing to ensure highest integrity, viability, and sterility of cellular product until release.
- Escalate important issues, as necessary, and ensure prompt resolution.
- Work as a part of the team to execute all necessary GMP runs for cell manufacturing in an accurate and timely manner.
- Perform accurate and error-free calculations of cell concentrations, cell and media dilutions and cell viability throughout the entire cell manufacturing process workflow.
- Able to execute all Department functions, such as maintaining suite, supplies, equipment, logbooks, and data in accordance with site SOPs and policies.
- Serve as On-The-Job-Trainer for a variety of job functions.
- Documentation of all activities to meet cGMP requirements.
- Execute document reviews and revisions. Daily record review, tasks, and databases. Actively provide feedback.
- Critical evaluation of processes, including foresight and thinking ahead.
- Complete preventative maintenance and work notifications tasks on time. Perform equipment testing and routine troubleshooting.

- Ensure tasks are executed with a method of prioritization - interpret production schedules and complete tasks accordingly.
- Perform timely consumption of materials and completion of quality documentation in appropriate systems.
- Identify deviations, aid in investigations/root cause analysis, and provide input on major/critical deviations.
- Work to complete documentation of deviations and events in appropriate systems
- Execute validation protocols with minimal supervision or direction.
- Participate in cross-functional teams to complete projects.
- Other duties may be assigned, as necessary.

Requirements:

- High school degree required. Bachelor's degree in Biological Sciences, Medical Technology, Applied Health Sciences or closely related field is preferred.
- 3+ years of relevant cGMP experience in a manufacturing pharmaceutical/biotech environment or related area
- Experience in aseptic cell culture processing in IOS 5 biosafety cabinets while using universal precautions for handling of human-derived materials preferred
- Experience in cell therapy manufacturing required
- Experience in cell therapy automation technologies, closed system culture vessels, cell washers, cell separation technologies for autologous/allogenic product manipulation preferred
- Experience in handling, propagation, isolation, activation and cryopreservation of human primary cells including T cells preferred
- Strict adherence to SOPs, GMP regulations, FDA guidance and ability to accurately complete associated documentation required
- Understanding 'why' and not just the 'how' of processes and practices
- Knowledge of cGMP practices required
- Knowledge of deviation investigations preferred
- Knowledge of cell culture and aseptic techniques required
- Mechanical Skills/ Analytical Skills/Method Automation
- MS Office
- Strong math skills
- Strong prioritization skills
- Detail oriented
- Strong communication skills with ability to read, write, and communicate in English
- Effectively multi-task
- Able to work in an environment of change
- Able to work independently and as part of a team
- Able to recognize problems developing, not just occurring

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 are proud of the team and environment we're assembling as we grow.