

Director of Cellular Products Laboratory

UPMC Hillman Cancer Center (Hillman) seeks a talented and experienced individual to lead the Cellular Product Laboratory (CPL). This is a very exciting time for a new director of CPL at the Hillman Cancer Center. The CPL director will be responsible for the overall scientific, clinical, administrative, and resource management of the CPL. The director will also provide technical leadership and scientific direction to maintain compliance to national and international regulatory standards and maintain accreditation and license status. The successful candidate should have the potential to bring in projects in cell and/or gene/viral therapies to provide a balance of academic and commercial business, as well as work collaboratively with both internal and external departments requesting services.

Hillman is strongly committed to leading the cellular therapies field, evidenced by a new, currently ongoing major space expansion (tripling the cGMP clean rooms and capacity), with the growth of the facility to a new 15,000 ft² building with the possibility of up to 10 total clean rooms, with flexibility of space to be guided by the new director. Expected completion date is summer 2020, providing an immediate opportunity for the candidate to provide important input into the design of the new facility space, layout and capabilities.

Hillman is strongly supported by UPMC and the University of Pittsburgh School of Medicine. The CPL is a shared resource currently supported by our NCI Cancer Center Support Grant (CCSG). The Hillman Foundation recently committed a large amount of continued support for our Center over the next 10 years. With our re-naming as UPMC Hillman Cancer Center, a new director of our center, and upcoming expansion of space for Hillman researchers, Hillman is unified and supportive of cancer research, prevention and therapy, especially cellular and gene therapies.

The CPL will be located in the City of Pittsburgh's rapidly developing biotech corridor at Pitt's Riverside campus, and closely linked to the Hillman Cancer Center based less than 10 minutes away. Hillman is a National Cancer Institute (NCI)-designated matrix cancer center focused on state-of-the-art cancer research, training the next generation of cancer researchers, and community outreach. In 2015 Hillman celebrated its 30th anniversary and the renewal of its 5-year NCI CCSG. Hillman has over 280 members, 7 scientific programs, 10 CCSG-supported shared resources, and a 2019 institutional funding base of over \$150 million. In 2019 the University of Pittsburgh ranked #4 in overall NIH funding. In 2019 it was named the nation's No. 7 hospital for cancer care in U.S. News & World Report's ranking. Pittsburgh is routinely ranked as one of the top most livable and affordable U.S. cities.

Responsibilities

- Brings strong scientific vision and track record to T cell and viral/gene therapies for academic and commercial application.
- Directs all operating procedures and administrative operations of the cell processing and cell manufacturing laboratories in compliance with relevant FDA regulations.
- Responsible for maintaining operating procedures and policies ensuring compliance with current Good Laboratory Practice (cGTP) regulations and applicable accreditation agency standards, including but not limited to FDA, FACT, CAP, and CLIA. Review SOPs written by other staff and ensure their completeness and accuracy.
- Manages CPL personnel establishing and maintaining the correct skill mix and adequate numbers of team members to provide continuity, efficiency and high-quality operations.
- Works closely with the QA team for validation of studies and quality management.

- Collaborates with the Medical Director on establishing and defining goals, objectives, and operational plans that support the clinical and scientific goals and objectives as they relate to advancing cellular therapy for the treatment of malignant and non-malignant disease.
- Determines the need for new or updated methodology and directs validation of new methods of production, associated quality control assays, and all associated standard operating procedures (SOP), master process records and staff training programs.
- Directly involved in product development, with specific thought in scientific direction of the facility and the field of cellular therapies.
- Directs the day-to-day activities of the cell production and manufacturing facilities and is actively involved in reviewing and improving operational procedures in the laboratory. Analyzes workflow and implements methods for effective and efficient operation.
- Directs program budget development and implementation with the support from the Hillman Cancer Center administration and fiscal teams in the preparation and implementation of clinical trial budgets, manufacturing budgets, and grant services budgets. This includes direct responsibility of the P&L for this facility.
- Serves as an expert, utilizing scientific knowledge and professional judgment in the design, implementation, and analysis of biologic product manufacturing.
- Directs processing and manufacturing activities and evaluates the integrity of processes and quality of products by monitoring safety, purity, potency, accuracy, and precision.
- Participates in the training and qualification of staff, while managing the creation and review of batch production and testing and generation of facility compliance documentation.
- Manages the team to ensure appropriate and timely product supply chain management as needed for production and manufacturing activities.
- Works with faculty to develop and manufacture novel cell therapies, including mesenchymal stem cells (MSCs), NK and NK CAR, Veto Cells, CAR T-cell, and exosomes.
- Develops and oversees a viral production facility within the CPL.
- Other responsibilities will include the management of a senior team.

Qualifications

- MD or PhD in medical technology, life sciences, engineering or equivalent is preferred.
- Extensive working and theoretical knowledge of current cellular and gene therapies is required.
- Experience in a cell production and manufacturing involving the complex scheduling and coordination of staff, materials and manufacturing operations is required.
- The ideal candidate will have both industry and academic experience, with at least 8 years of combined experience, particularly in a cGMP compliant work environment
- Industrial background is preferred, but contacts within relevant industry is a must.
- Candidate must be able to work in an academic environment while maintaining commercial and clinical rigor to the facility.
- >7 years management experience:
 - Management of larger complicated teams is highly recommended
- Experience with AATB, AABB and or FACT accreditation is preferred.
- Experience in interactions with federal agencies, i.e. FDA.
 - Specifically, interactions that involve filing INDs, etc.
- Excellent communication and organizational skills and superb attention to detail.
- Experience in clinical research management and oversight, including project management in a dynamic research setting.
- Experience in developing and implementing multifaceted projects.
- Preferred candidate brings a history and potential transfer of externally funded academic or commercial projects.