Center for Human Therapeutics cGMP

About Us

The Center for Human Therapeutics (CHT) facilitates bench-to-bedside translational of preclinical biologics at state of the art Good Manufacturing Practices (cGMP) compliant facility at the University of Virginia (UVA). The facility is designed in accordance with U.S. Food and Drug Administration (FDA) as well as other relevant requirements for controlled clean room manufacturing environments and aseptic processing. Facility includes 6 manufacturing rooms (five ISO 7 and one ISO 6 clean rooms) controlled access corridor, office and support space. The CHT cGMP is a dedicated multi-use clean room complex for the manufacturing and processing of cellular products, preparation of islet cells for transplantation, production of monoclonal and bispecific antibodies, manufacturing of viral vectors and production of solution phase nanoparticles for human clinical use.

Instrumentation

CHT cGMP has six cell therapy suites ready for use, are outfitted with BSL2 biosafety cabinets, bench top centrifuge, inverted microscope, and some suits are outfitted with incubators. In addition, some rooms have one, two or more of the listed instruments.

- **Xuri Cell Expansion System**
  Delivers an automated, controlled expansion environment for the growth of cell products
- **Sysmex XP-300 Cell Counting System** Provides a CBC with 8 reportable parameters and 3-part WBC Differential
- **Baxter Fenwal and ReadyProcessor Cell Harvesting Systems**
  Efficient systems for harvesting a large number of cells (>100 billion)
- **Elutra Cell Separation System Counter**-flow centrifugal elutriation to separate the different cell types
- **CliniMACs Prodigy**
  Offers a flexible, closed and automated platform with capability to manufacture various cell types on a single device and within single process setup

Our Services

Manufacturing and Quality Control Services: The cGMP personnel have extensive experience in cell manipulation, growth, and transduction of lymphocytes and other immune cells. The cGMP core provide material processing, material modification, material production, material analysis, material maintenance, and material support services. Some examples include:

- Activation and expansion of patient T lymphocytes (Material production service)
- Quality control and quality assurance services for clinical cellular product and biologics (Support service)

Consultation Services:
The Facility Scientific Director and staff provide one-on-one consultations to investigators in planning and conducting clinical trials and assist in the preparation of Investigational New Drug (IND) applications to the FDA. Review of cellular and biologic product manufacturing process and SOP development for clients.

Education and Training Services:
The Facility Scientific Director and Program Director participates in Cancer Center's seminars to spread the awareness about the cGMP facility at UVA Campus, and delivering webinars hosted by the biologic product related companies. CHT cGMP staff provide full training to new users.

The CHT cGMP facilitates
bench-to-bedside
translation of biologics

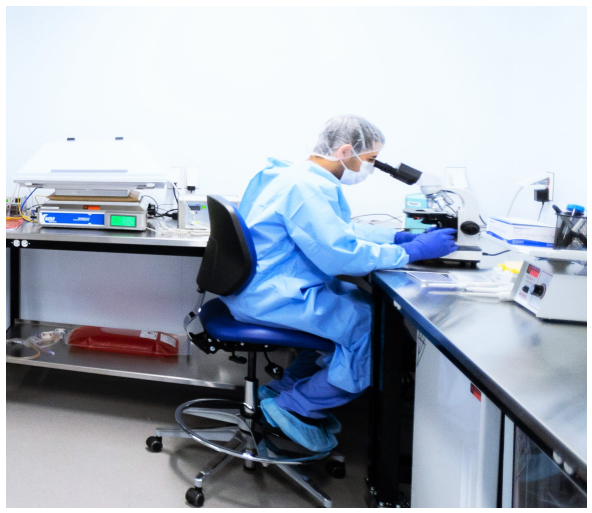
Enhancing Research, Rigor and Reliability

Our Team

Archana Thakur, PhD - Director
Associate Professor of Medicine Scientific

Dana Schalk, BS, MBA - Regulatory and Facility Manager

Lawrence Lum, MD, DSc - Faculty Director
Professor of Medicine



Contact

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Request services on:
uva.corefacilities.org/account/login

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UVA Health
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