

# Upstate Stem Cell cGMP Facility

## Upstate Stem Cell cGMP Facility (USCGF)

The USCGF at the University of Rochester Medical Center offers 3 state-of-the-art manufacturing suites (ISO 6) and highly skilled technical personnel to University Investigators, Academic and Industry partners for a diverse palette of products :

## SERVICES

- **Process development and scale-up for GMP manufacturing and Clinical trials (Phase I/II)**
  - **Stem cells (Adult, ESC, iPSC, MSC) for autologous and allogeneic transplants**
    - Suspension/Adherent
    - Master/working cell bank options
      - Control rate freezer for cryopreservation
  - **Immune cells (PBMC, T-cells, Dendritic, Lymphocytes)**
    - Genetically modified T cells (CAR-T)
  - **Monoclonal Antibodies and recombinant protein production**
    - Bacterial/Mammalian host
    - 25L fermentation/cell culture
  - **Gene Therapy Vector production**
    - Lentiviral or retroviral transduction
  - **Quality control In-process and release testing of intermediate and final products**
    - Gram-Stain; Endotoxin (LAL test), 14-d Sterility test, Real-Time PCR for Mycoplasmas (qPCR)
  - **Vaccine formulation and vialing**
- **Analytical methods development and qualification**
- **Quality management system supporting all aspects of manufacture and testing of clinical-grade materials**
- **Regulatory support including CMC documentation for IND filings**

In operation since 2012, the USCGF has a proven track record for producing high-quality clinical-grade cell therapy materials for both pre-clinical animal studies, including safety/toxicology studies, and early phase human clinical trials.

## Contact Us

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- **ISO Class 5** (Class 100)
- **ISO Class 6** (Class 1,000)
- **ISO Class 7** (Class 10,000)
- **ISO Class 8** (Class 100,000)