

Systems

Engineered Manufacturing Systems (Test-Beds)

MSCs for immune modulation and musculoskeletal applications

T cells for cancer immunotherapy applications

iPSC-cardiomyocytes for cardiac regeneration applications

- Integrated, closed manufacturing system with real time analytics of CQA and CPP for scale-up or scale-out manufacturing
- Education, outreach, inclusivity, and workforce development
- Predictive systems analysis of therapeutic cells
- Best practices, consensus analytics, and industry standards
- Social and regulatory policy, healthcare economics

Products & Outcomes:

- Transformative innovations in cell manufacturing technologies
- Inclusive workforce
- Industry standards

Industry, Clinicians, Patients, NIST, FDA, & Reimbursement Experts

Requirements

Barriers

- Predictable safety and efficacy
- Lack of quality-driven manufacturing
- Regulatory pathway, and standards
- Large-scale, low cost, manufacturing
- Trained workforce

TECHNOLOGY INTEGRATION

Enabling Technologies

Engineered Manufacturing Systems (Test-Beds)

MSCs from bone marrow and cord tissue

Therapeutic T cells

iPSC-derived cardiomyocytes

Thrust 1

- Big data analytics tools for predicting cell function
- Multi-omics platform integration

Thrust 2

- Disease/tissue-on-a-chip
- Biosensors, imaging, in-line monitoring

Thrust 3

- Process modeling and supply chain simulations
- Engineering biomaterials and bioreactors

Deliverables:

New tools and technologies

Barriers

- 1 Lack of rapid, physiologically relevant potency/safety assays
- 2 Lack of real time monitoring of CQAs and CPPs during manufacturing
- 3 Difficult scale-up/out, supply chain/logistics

TECHNOLOGY BASE

Fundamental Knowledge

Thrust 1

- New systems-driven multi-omics pipeline for cell characterization
- Multi-variate discriminators of cell quality (potency and safety)

Thrust 2

- Minimal models of tissue/disease
- *In vitro* vs. *in vivo* safety/potency

Thrust 3

- Effects of materials and bioreactors on cell quality
- Process/supply-chain and logistics requirements for living cells and reagents

Deliverables:

New scientific knowledge

Barriers

- 1 Lack of Critical Quality Attributes (CQA) and Critical Process Parameters (CPP)
- 2 Poor understanding of *in vitro/in vivo* correlation of cell properties/function
- 3 Lack of understanding of (a) scaling effects on cell quality, (b) supply chain

KNOWLEDGE BASE