Establishing a cGMP Advanced Biofabrication Facility

Lead Contact: Roland Kaunas (rkaunas@tamu.edu, 979-845-2412)

Departments: Biomedical Engineering, Cellular and Molecular Medicine (COM)

Key Participating Units: COE/TEES, VTPP and COM

Requested Amount: $1.2M

Summary: A multidisciplinary team of PIs representing three colleges at Texas A&M University (TAMU), namely, Engineering, Medicine and Veterinary Medicine, as well as the Center for Cell and Organ Biotechnology and National Center for Therapeutics Manufacturing (NCTM), request research development funds to establish a shared **Advanced Biofabrication Facility (ABF)**. *The funds are requested for a Generation 2 Walker Barrier Systems Mobile Clean Room to be housed in the NCTM focused on the production of clinical-grade products involving human cells compliant with current Good Manufacturing Practices (cGMP).* The ABF will also provide a unique environment for workforce training in the rapidly growing cell-based therapeutics industry. This expands the NCTM's current technical training and professional development programs for the biopharmaceutical and vaccine manufacturing industries.

The proposed ABF is a vital addition to the ~$250K of equipment and instruments pooled from participating departments and being installed as part of 800 sq. ft. of space allocated in the NCTM with multi-year staff support from NCTM (for workforce training) and TEES Technology Commercialization and Entrepreneurship (for tech transfer and commercialization). The proposed facility and services will impart TAMU with the capability to create and commercialize bio-devices involving human cells within one or more steps of a manufacturing process for fabricating engineered tissues for implantation and organ-on-a-chip technologies for drug discovery and toxicology.

The proposed ABF is closely aligned with TAMU's strategic interdisciplinary thrusts, especially related to Healthcare and Materials & Manufacturing. A cGMP facility dedicated to biofabrication is pivotal to boost and sustain its nascent success in collaborative ventures (e.g., recent grants from NSF, NIH, and CASIS plus proposals to DOD towards medical innovations based on advanced manufacturing technologies applied to regenerative medicine and organ-chip technologies), as well as to bolster TAMU's position as the Southern U.S. hub of a $80M Advanced Tissue Biofabrication Manufacturing Innovation Institute (ATB-MII) to advance state-of-the-art tissue manufacturing innovations in cell and biomaterial processing, bioprinting, automation and non-destructive testing technologies. As such, this effort will be a natural collaboration between several COE, COM and VTPP departments. The ATB-MII is aimed at increasing U.S. competitiveness in advanced tissue biofabrication manufacturing by encouraging insertion of disruptive technologies into multiple biotechnology sectors, streamlining integrated testing technologies and ultimately reducing the barrier to entry for new inventors.

The ABF will work synergistically with several existing core facilities at TAMU to expand the overall impact of research in regenerative medicine, advanced manufacturing and toxicology. For example, materials developed and processed with the support of the Center and Materials Characterization Facility, Institute for Manufacturing Systems, Polymer Technology Center, Process Engineering R&D Center can be brought to the proposed biofabrication facility to be combined with human, mouse and rate mesenchymal stem cells or human induced-pluripotent stem cells distributed by the Institute for Regenerative Medicine.