

Grant Title: Bioreactor for GMP manufacturing of Tissue Engineered Vascular Graft for Pediatric Regeneration

Grant Number: RMM-2016-BB-05

Requester: Zeeshan H. Syedain, PhD

Project Timeline: June 1, 2016– May 30, 2017

Brief description of project:

Where did this project take place?

Project work was performed at the Molecular and Cellular Therapeutic (MCT) facility on the University of Minnesota St Paul Campus, scientific director Dr. David McKenna. GMP bioreactor were manufactured, sterilized and eventual validation study was performed at the facility. Regulatory consulting was provided by Access Biomedical LLC.

People impacted by project and where they are from:

In current project impact was primary for Minnesota business including contract testing facility (Pace Analytical), regulatory consulting (Access Biomedical) and MCT facility.

What was the outcome of the project? (Did the project work the way you expected it to? What were the successes? What were the failures? How did it impact regenerative medicine in Minnesota?)

The project was successful in developing a manufacturing document with review by regulatory consultant and validation work performed at a GMP manufacturing facility (MCT).

There were few setbacks during early part of the project. Original goal was to work with a local bioreactor manufacturer to customize their current bioreactor system, however in consultation with clinicians it was concluded bioreactor size needed to be increased. This required custom chamber design, which was engineered and eventually manufactured and assembled at the MCT facility. The new design was validated with 7 week culture of engineered tissue at the MCT GMP manufacturing facility.

Going forward the new design and validated process will be used to develop pre-IND regenerative pediatric vascular graft and eventual clinical use. Prof. Robert Tranquillo and David McKenna have received NIH PACT contract to cover the cost of proposed pre-IND work.

Please list any of the following that have resulted from your Regenerative Medicine Minnesota grant funding:

- Publications and/or manuscripts submitted for publication
- Disclosures/patents
- Other grant applications and/or awards

MCT facility which was used in current project to develop and validate GMP bioreactor and manufacturing has received NIH PACT contract funding to continue development of vascular graft towards clinical trial

Responsible Spending:

Please let us know how you spent the money. Any unspent funds must be returned.

Main expense was GMP manufacturing of bioreactor and validation with cost split between culture supplies and technician labor (sub-contract with Fairview). Regulatory consultant and payroll were the remaining budget expenses.

University of Minnesota, Biomedical Engineering Department is currently finalizing the budget report but expects no unspent funds. Once the grant account is closed final expense report can be retrieved from University Financial system.