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School of Biological and Health Systems Engineering

Characterizing AT-102: A Viable Cultured Cardiac Matrix

Carlos Chang, PhD

Technical Director, R&D and Manufacturing,
Avery Therapeutics, Inc.

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Faculty Host: Sydney Schaefer

Abstract Heart disease is one of the greatest causes of morbidity and mortality in the world. In 2020, according to the CDC, 697,000 Americans died from heart disease. This staggering number represents 20% of all deaths. To help address this critical need, Avery Therapeutics is developing our first product, AT-102, a viable cardiac matrix composed of fibroblasts and iPSC-derived cardiomyocytes. AT-102 is a cell-based therapy intended to improve cardiac function of tissues that have suffered ischemic damage. The ability to manufacture and deliver a quality biologic product to future patients is a major research focus. Internally, Avery Therapeutics has been working with commercially available quantitative assays to evaluate AT-102 production. An emphasis has been placed on non-destructive evaluation methods that permit broad use during product manufacturing. These assay systems focus on soluble factors produced during culture. Factor production trends are being used to characterize and determine key manufacturing timepoints. The presented work will share some of our evaluations of AT-102 characterization following a variety of test conditions. Test samples were physically shipped to and returned from locations ranging in temperature from -11C to 36C. Other samples were tested after storage at various temperatures for multiple days. Following testing, collected data suggests AT-102 maintains viability and has the capacity to return to baseline properties.The results of this testing provide evidence of the resilience of our AT-102 product. AT-102 are compatible with a wide range of shipping and storage conditions, permitting flexible handling and preparation conditions for our end users. In addition, the collected information establishes a strong foundation for developing final shipping and handling protocols of our future clinical products.

Biosketch Carlos C Chang, Ph.D., has contributed to a wide range of research, translation, and product development in the medical device and regenerative medicine fields. From start-ups to space stations, Dr. Chang's work has encompassed the organization of biological and synthetic materials to yield improved treatments for current and future patients. In the cardiovascular space, Dr. Chang has a long history of collaborating with both academic and industry partners. This work has included the development of various large-animal models of stroke, cardiac and musculoskeletal ischemia. These test systems have been used to evaluate a breadth of early-stage pharmaceutical, cell, and device therapies. In the medical device field, Dr. Chang has led teams that developed tissue-derived medical devices indicated for repairing structures in and around the heart. Internationally and FDA cleared, these devices are currently used to treat a wide range of pathologies from congenital heart defects to vessel and valve repair. Other work has been more future focused, investigating the influence of microgravity on 3D bioprinting of vascular and cardiomyocyte structures as well as the long-term effects of fractional gravity and radiation on biological systems. In his current role as Technical Director, R&D and Manufacturing, Dr. Chang is leading the product development efforts of Avery Therapeutics' first product, AT-102. Currently in preclinical phase, AT-102 is a viable cardiac matrix of cardiomyocytes and fibroblasts targeting the improved function of damaged, ischemic ventricular tissue. Dr. Chang and the Avery Therapeutics Team are excited to bring this unique product to market to help a variety of patients in need.