



Fabio Triolo, DdR, MPhil, PhD
The Clare A. Glassell Distinguished Chair
Director, Cellular Therapy Core
Professor, Pediatric Surgery
Professor, Clinical and Translational
Sciences

Dr. Triolo has a broad background in clinical-grade cell-based, tissue-based and combination product manufacturing for regenerative medicine applications, and extensive experience in compliance with American and European current Good Manufacturing Practices (cGMPs). He has 15 years of experience establishing and directing Investigational New Drug (IND)-dedicated cell production facilities compliant to European and American cGMPs in Europe and in the US and has supported >20 cellular therapy clinical trials aimed at adult and pediatric patients and conducted in Europe and in the US based on various cell-based products (e.g., fetal liver progenitor cells, pancreatic islets, bone marrow and umbilical cord derived mononuclear cells, adipose tissue, umbilical cord tissue and bone marrow derived mesenchymal stromal cells, regulatory T cells, genetically modified T cells). In collaboration with Biostage, Inc., his team produced a FDA-compliant adipose tissue derived MSC-seeded esophageal implant that was the first tissue engineered esophagus ever implanted in man, and he was the first to publish specific risk analysis approaches and procedures applicable to cell therapy manufacturing and to provide a specific model for guidance of cell transplantation centers and cell processing facilities, especially if approaching risk management for the first time. He directs the Cellular Therapy Core at UTHealth, and functions as a bridge between scientists and clinicians, enabling the translation, scale-up, and validation of promising new therapeutic technologies developed by scientists at a preclinical level, into clinical-grade processes that can be used to manufacture cell-based and/or tissue engineered and/or combination products for clinical applications. He also ensures that such processes are designed/translated in compliance with national and/or international regulations according to the nature of the trial. For the last decade, he has been manufacturing cell-based products at UTHealth to support multiple single- and multi-center clinical trials aimed at developing cell-based therapies to improve neurological conditions, such as anoxic brain injury at birth, cerebral palsy, traumatic brain injury, stroke, amyotrophic lateral sclerosis (in collaboration with Dr Stan Appel of Houston Methodist), and treatment-resistant bipolar disorder, all of which are still unmet medical needs.