Standards are a powerful force in the protection of public health and safety, the development and commercialization of new technologies, and facilitation of national and international commerce. In the field of regenerative medicine, the need for standards has emerged as a common gap from various workshops, meetings, and discussion forums.

Here we provide an update on multiple collaborative efforts between the U.S. Food & Drug Administration (FDA) and the National Institute of Standards and Technology (NIST), to support standards development for regenerative medicine R&D, manufacturing, and translation. Collaborative efforts include coordinated workshops, leadership and participation in standards development efforts within relevant SDOs, and joint research projects. These collaborations leverage NIST expertise in measurement sciences to address specific analytical scientific challenges as well as leveraging FDA regulatory expertise in regenerative medicine products to ensure that the science and standards developed address significant regulatory challenges that recur across the field.

This talk will focus on joint FDA-NIST efforts to develop standards within ISO/TC 276: Biotechnology, and several collaborative projects on cell counting and cell viability to support the development of standards. Cell viability is an important quality attribute often used as a manufacturing in-process control or a release criterion for cell therapy products. Assurance for cell viability measurements has been particularly difficult due to ambiguities in the definition of viable cells as well as measurement challenges associated with quantifying cell health. The joint FDA-NIST project in cell viability aims to provide strategies for establishing validation protocols for cell viability measurements.