

2020 CTTE SHORT COURSE

“Cell-Based Therapies and Tissue Engineering”

Keynote Lecture

“The Regulatory Environment for Regenerative Medicine: A Changing Landscape”

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Abstract

Since the time of Robert Langer and Joseph Vacanti’s landmark paper on “Tissue Engineering” in 1993, thousands of biologists, clinicians and engineers have sought to develop Regenerative Medicine products to address some of the most challenging and pervasive problems in clinical medicine. As we evolved from the “Age of Chemistry”, through the “Age of Engineering” and now into the “Age of Biology”, the pace at which our knowledge expands has grown exponentially. While this has created a wide array of incredible laboratory-based solutions that hold promise for treating patients, industrialization of these concepts and navigation of the evolving regulatory landscape represents a formidable challenge. The process of Product Development is very different from the work typically done in university settings, and most early-stage companies are not equipped to overcome the myriad of challenges necessary to garner regulatory approval of these products in the United States or elsewhere. In response to the growing sophistication, complexity and growing demand for such products, the US Food & Drug Administration (FDA) has crafted a series of Guidance Documents and other policies to help provide a roadmap for those seeking to commercialize products. Naturally, there is some controversy surrounding the interpretation of these rules, led primarily by those who are currently not following them, or those who wish the rules were different. Importantly, after disseminating these rules nearly 3 years ago, with a discretionary enforcement period aimed at encouraging “bad actors” to correct their practices, in November of 2020 the rules will be in full effect. At the close of the discussion, participants will have a greater understanding of the multi-year, multi-step, interactive process required to commercialize new products, with an emphasis on understanding the new paradigm for regulatory approval by the FDA.

Monday, August 10, 2020 Clapp 108.
4:30 – 5:30 p.m.

(This lecture is open to the University and its Affiliates)