

Stephen F. Badylak, DVM, PhD, MD
Strategies for Commercialization of Regenerative Medicine

Abstract:

Biomaterials are intended to replace damaged or missing tissues. Such materials can be synthetically or naturally occurring in origin and the clinical acceptance of these biomaterials is a function of their mechanical properties and the host remodeling response. The clinical translation of a novel biomaterial from the time of discovery and development in the laboratory to the use in patients is dependent upon a variety of factors including intellectual property protection, the ability to obtain regulatory approval, mechanical and material properties, clinician acceptance, and third party reimbursement issues. The use of xenogeneic extracellular matrix as a biologic scaffold material for a variety of clinical applications will be used as a prototype example for discussion of each of these variables.