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Key Gaps in the Commercialization of Regenerative Medicine Products

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Abstract

While promising for human health, Tissue Engineering/Regenerative Medicine (TE/RM) products face many challenges on the long road to commercialization. These include technical, manufacturing, financing, regulatory, reimbursement, distribution and clinical acceptance issues. The Industry Committee of TERMIS-Americas is dedicated to educating the TERMIS membership regarding these challenges, so that they may ultimately be surmounted. Over the past four years, membership survey assessments have been made of the degree of awareness of academic and business challenges, regenerative medicine financing trends and FDA science submission requirements. The results are published in *Tissue Engineering*. Workshops have also been and are being held at TERMIS meetings by the Industry Committee to address what has been learned. An important issue that has been identified is that when the initiation of the development of TE/RM translational products occurs in academia, it is often accompanied by an inadequate understanding of clinical, business process (including marketing), financing and regulatory requirements. In this presentation, those issues will be reviewed and methods will be proposed for their resolution.