

Regenerative Medicine

Steps to Accelerate Development

Table of Contents

Introduction

- Understanding the FDA’s Regulatory Framework for Regenerative Medicines 4**
 - A Brief History of the FDA and HCT/Ps..... 6
 - How the FDA Defines Minimal Manipulation 8
 - How the FDA Defines Homologous Use..... 12
 - The “Same Surgical Procedure” Exception 14
 - Emerging Regulatory Issue: Cleared Medical Devices 15
- Recent Enforcement Actions, Regulatory Priorities 17**
- A New Fast-Track Approval Process 19**
 - How to Apply..... 20
- Bringing an HCT/P to Market 22**
 - Preclinical and Clinical Studies..... 22
 - IND v. IRB 23
 - Meeting with FDA Officials..... 23
 - Foreign Clinical Trials..... 24
 - Marketing an HCT/P Outside the U.S. 25
- Appendices 26**
 - A. *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*
 - B. *Same Surgical Procedure Exception Under 21 CFR 1217.15(b): Questions and Answers Regarding the Scope of the Exception*
 - C. *Evaluation of Devices Used With Regenerative Medicine Advanced Therapies*
 - D. *Expedited Programs for Regenerative Medicine Therapies for Serious Conditions*
 - E. *FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND: Frequently Asked Questions*