Understanding the FDA's Regulation of HCT/Ps and Successful Product Development Strategies

Description:  In 1997, the FDA proposed a comprehensive regulatory program for Human Cells, Tissues and Cellular- and Tissue-Based Products (HCT/Ps) outlining the registration and listing procedures for HCT/Ps. This program also differentiates between HCT/Ps that will be regulated via the traditional pathway and those that will undergo approval as new drugs, biologics or devices.

In this seminar, we'll discuss the historical context for the use of HCT/Ps in medicine as well as how the HCT/P market is evolving. You will be shown examples of the FDA-approved use of HCT/Ps and what is required for successful product development. This course will also provide an overview of the health authority regulating HCT/Ps, discuss the regulations that govern HCT/Ps, discuss potential product development strategies and provide an overview of product development in the United States.

Learning Objectives:

Upon completing this course, participants will better understand:

- The FDA's regulatory approval process for HCT/Ps
- Keys to successful product development of HCT/Ps
- Application of “Minimal Manipulation,” “Homologous Use” and “Chemical Action”
- Currently approved use of HCT/Ps in medicine
- The drug and biologic approval process
- Nonclinical requirements to support product development
- Challenges of product characterization and specifications with respect to HCT/Ps
- Requirements for compliance with good tissue practice, good manufacturing practice and good laboratory practice
- FDA enforcement actions
- The global regenerative medicine market
- The One Health Initiative and its impact
- HCT/Ps and translational medicine
- Future approaches for regulatory approval of HCT/Ps in regenerative medicine


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