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Regulatory considerations for regenerative therapeutics: US perspective

The regulation of human cells and tissues by the United States Food and Drug Administration (FDA) originated with the 1902 Biologics Control Act and the 1944 Public Health Service (PHS) Act. These initial acts were put into place to ensure purity of serum and vaccines and to control the spread of communicable diseases, respectively. As the use of human cells and tissues has expanded, FDA was faced with the dilemma of differentiating between their uses in the practice of medicine versus in the manufacture of a product. Under the authority of Section 361 of the PHS Act, FDA introduced a comprehensive regulatory program in 1997 for human cells, tissues and cellular and tissue-based products (HCT/Ps). This consolidated regulatory approach covered all cells and tissues and was tiered and risk-based to allow for less regulatory evaluation of products determined to present a minimal risk to patient safety. In 2005, this regulatory program was implemented in rules codified under 21 CFR Section 1271. These rules defined the conditions that must be met for an HCT/P to be regulated solely under the PHS Act (called 361 HCT/Ps) and those that would be defined as biological products that would also be regulated under the Food, Drug and Cosmetic Act requiring market clearance (called 351 HCT/Ps). This determination and the potential regulatory pathways for these cutting edge technologies is often complex and understanding these regulatory pathways and the definitions surrounding them is critical to successful product development in the United States. Beyond the challenges of navigating the regulatory maze for new regenerative therapeutics, sponsors must also adopt new approaches to evaluate safety and efficacy, and to identify measurable quality attributes regarding product safety, quality and potency. FDA is actively engaged in providing guidance and expedited approval pathways in order to bring these discoveries safely forward to benefit patients.

Biography

Debra Aub Webster has over 20 years of experience in pharmaceutical research and the regulatory environment. She has started her regulatory career with the US FDA as Reviewing Toxicologist/Pharmacologist. As a Principal Scientist in Regulatory Affairs and Product Development with Cardinal Health Regulatory Sciences, she leads projects for biologic and regenerative medicine product development programs. In this capacity, she provides guidance on clinical, nonclinical and regulatory aspects of strategic product development, author's regulatory documents and acts as the Regulatory Representative for sponsors in interactions with the FDA.

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