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Regenerative medicine-From promise to patient

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The expansion in the use of human cells and tissues from their functions in practice of medicine, for repair or replacement, to their use as a manufactured product intended to treat an indication or condition has led to increased regulatory oversight by FDA. 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 is 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. Under these rules, some HCT/Ps are defined as biological products, requiring market clearance. The potential regulatory pathways for HCT/P-derived technologies is often complex, and understanding these regulatory pathways and the definitions surrounding them is critical to successful product development. Navigating the regulatory path, from scientific discovery to initiation of clinical investigations is challenging. These challenges include determination of the appropriate regulatory pathway and understanding the requirements regarding demonstration of safety and efficacy and identification of appropriate quality attributes regarding product safety, quality, and potency. FDA has issued numerous guidance documents and offers several expedited approval pathways in order to bring effective discoveries safely forward, to benefit patients. Successful strategies for achieving this goal include identifying critical information gaps with respect to the appropriate regulatory pathway; informed clinical, non-clinical, and quality development plans; maintaining a Target Product Profile; and successful interaction with the appropriate review division within FDA.

Biography

Debra Aub Webster has over 20 years of experience in Pharmaceutical Research and the Regulatory Environment. She 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 is the Project Lead 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 regulatory documents, and acts as the regulatory representative for sponsors in interactions with FDA.

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