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Regulatory roadmap for initiating a cell therapy drug into clinical trials in the US

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Exciting progress has been made in the development of cell therapy, and experimental research has brought forward novel treatment opportunities for immune cell therapies, stem cell therapies, and gene-modified cell therapies. Clinical development of a cell therapy drug is challenging, requiring understanding of controlled manufacturing, relevant nonclinical pharmacology and safety studies, and clinical risk factors. For initiating clinical trials in the United States, regulatory requirements for investigational cell therapy drugs are more stringent than those with other investigational drugs. This talk will highlight these requirements, including submissions to regulatory authorities and the required non-clinical studies.

Biography

William Lee received his BA from Johns Hopkins University, and PhD from Cornell University Graduate School of Medical Sciences. He has twenty years of research and industry experience. His focus is on gene therapy with retroviral vectors, adeno-associated viral vectors and DNA vectors. He spent 9 years at the gene therapy start-up firm, Viagene, Inc., followed by 2 years at Chiron. In 1999, he joined Cato Research, in Durham, North Carolina, where he is currently Vice President, Regulatory Affairs. His projects have included the design of Phase 1 and Phase 2 protocols for a gene therapy drug and interactions with the FDA and NIH/OBA. Currently, he manages projects involving regulatory strategy and submissions of investigational new drug applications and marketing applications for biologics and drugs.

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