



IEEE Miami Section Invited Seminar Announcement

“Biomedical Regulatory Strategy for FDA Approval: Regulatory Consideration in Medical Device and Biotechnology Development”

Speaker: Jeremy D. Ollerenshaw, PhD

Date: Thursday, November 10, 2022

Lecture: 5:00 PM ET

Zoom: <https://fiu.zoom.us/j/98265123186>

Meeting ID: 982 6512 3186 **Passcode:** 259WgL



Abstract:

This talk will focus on the requirements of the FDA for simple and complex biomedical products that may include bench, preclinical and clinical studies, validation and verification studies, product stability and biocompatibility. Other requirements will also be discussed such as product packaging and labeling. These are all aspects that are addressed in FDA submissions and are usually handled by a broad team. We will discuss how these all fit together. Additionally, the strategy of making applications to FDA for review and approval of biomedical products will be covered. This will be an interactive discussion, with plenty of time for Q&A, of regulatory considerations in developing medical devices and biotechnologies for clinical use, and for their approval by the US FDA.

Speaker's Bio

JEREMY D. OLLERENSHAW, PhD obtained his PhD from the University of Leicester in the UK and came to the US to take up his post-doctoral research post in the Division of Cardiology at Emory University in Atlanta, and later attaining the position as Instructor in Medicine in the Division. Staying in the US, his move into the pharmaceutical and medical device industries has given him various R&D leadership roles over the past 25 years. He has played an integral part in drug and medical device product development and regulatory filings internationally and has published more than 60 scientific research articles in medical and scientific journals. He has been awarded research grants from NIH, the American Heart Association, and the British Heart Foundation.

Dr. Ollerenshaw also has an entrepreneurial interest in developing treatments in neurological illness, and in 2011 Jeremy founded the Neurobiology Foundation, a 501(c)3 non-profit organization, that assists in the development of promising therapeutics to treat psychotic illness, and in 2016, he co-founded BetaBlue, Inc. a developmental stage company developing therapeutics to treat neurological illness.

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