Developing and Marketing Botanical Drugs in the United States

The United States has the largest pharmaceutical market in the world, as well as a strong demand for the use of botanicals as medicine. However only two botanical drugs are currently approved for use in the USA, Veregen® (sinecatechins) and Mytesi™ (crofelemer). The unique American historical use of plants as drugs in which adulteration, mislabeling, false claims, and even the development of tobacco have all contributed to shape its regulatory policies and perceptions far differently than other countries. Unlike other countries, the United States has no separate regulatory category for traditional or herbal medicines. Instead these products are considered crude drugs which may be developed as either a food (includes dietary supplements), a drug, medical device, or cosmetic. This cross-cultural confusion is worthy of exploration for those wishing to enter the US marketplace and should not be overlooked.

This presentation is intended to give the participant an understanding of the regulatory paths for development of a botanical product based on the four US guiding principles for classification: Intention of Use, Route of Administration, Formulation, and Risk. Graphs will assist the learner to quickly differentiate characteristics of regulatory categories emphasizing dietary supplements, standard single chemical entity drugs, and heterogeneous botanical drugs. Unique chemistry and manufacturing controls of each classification will be discussed, focusing on those required of heterogeneous drug products under the *Guidance for Industry Botanical Drugs* issued by the FDA in 2004 and revised in 2016. The speaker will present to the attendee throughout the presentation an understanding of the culture and history of the American market to understand hidden barriers for product approval of botanicals as drugs as well as consumer expectations and demands of botanicals.



Dr. Christina Marrongelli is a graduate of the University of Mississippi, School of Pharmacy with a BS in Pharmaceutical Sciences, and Doctorate of Pharmacy. Marrongelli has rare experience and training in business, regulatory affairs, clinical services, and pharmacognosy. She achieved advanced training in dietary supplement quality control and conducted research in drug discovery to drug development of natural products leading to patent positon in conjunction with the National Center for Natural Product Research. Marrongelli holds appointments as Adjunct Professor at the University of South Carolina School of Medicine, Department of Drug Discovery and Biomedical Sciences, serves as Chair for the Naturopathic Doctors Formulary Council for the Maryland Board of Physicians, and is an advisory member of several laboratory and public health working groups. Marrongelli is CEO of ECHealthcare™ and Integrative Pharmacy Solutions located in Washington DC. Her organization provides expert advisement in business development, regulatory affairs, and education to assist academic, healthcare, research, and government agencies in the field of natural product development and cannabis research. Please contact at Marronge@musc.edu.

