Summit on Challenges and Solutions in Quality & Safety of Homeopathic Drug Products

June 27-28, 2019 | Hilton Baltimore Inner Harbor

Regulatory Track: Workshop 1
10:15–11:45 a.m.

Homeopathic Product Substantiation from Concept to Shelf

Presented by Susan J. Hewlings PhD, RD, Director of Scientific Affairs for Nutrasource and Professor at Central Michigan University

In light of FTC's disclaimer request, what can the homeopathic industry learn from the supplement industry? When bringing products to market, it is essential to build a platform that allows all information generated to be available for future use. Manufacturers and labelers will learn about factors in substantiating claims and which business partners are held responsible in the eyes of the law. FDA's six new risk-based enforcement categories are examined in-depth with examples. FTC history and "no-nos" are reviewed before closing with a comparison of regulations for homeopathy in the U.S., Canada and the U.K. to provide worldly guidance.

What You Will Learn:

- Substantiation per FTC and FDA guidance.
- How to develop a substantiation file.
- What types of claims you can make.
- How to navigate the regulatory environment while still providing true homeopathic products.

About the Presenter

Dr. Susan Hewlings received her PhD in nutrition her BS in nutrition and her MS in exercise physiology, all from Florida State. She is a Registered Dietitian, a full- time professor at Central Michigan University, and Director of Scientific Affairs for Nutrasource, a full service CRO serving the dietary supplement, pharmaceutical, cannabis and CBD industries. She is Co-Founder of Substantiation Sciences LLC where she provides science and nutrition consulting services and medical writing for the dietary supplement, cannabis and medical industries. She has published many articles and book chapters on sports nutrition, dietary supplements and CBD/Cannabis.