



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

June 27-28, 2019 | Hilton Baltimore Inner Harbor

### **Safety Track: Workshop 1**

10:15–11:45 a.m., Stone Meeting Room

#### **Pharmacovigilance**

*Presented by Richard Kingston, PharmD, President, Regulatory and Scientific Affairs, [SafetyCall International, PLLC](#), & Clinical Professor of Pharmacy, University of Minnesota*

This workshop will be presented in a live interactive video stream that will allow for real-time Q&A.

Despite the inherently wide margin of safety for FDA regulated homeopathic drugs and dietary supplements, product related safety issues can arise. Current regulatory requirements for mandatory reporting of serious adverse events were designed to help regulators identify the most egregious of safety issues. But simply meeting regulatory requirements may not aid the manufacturer in the detection and mitigation of the most serious threats affecting a company's product and brand. This presentation reviews best practice post market surveillance at a corporate level, and how implementation can aid in the detection, management, and mitigation of the most serious product safety threats a company may face.

#### **What You Will Learn:**

- Key principles behind Best Practice Post Market Surveillance
- To think outside the box in the application of safety signal detection
- How to identify and separate "background noise" from emerging threats when analyzing spontaneously reported adverse events
- How to package and communicate the adverse event experience into a positive product safety message

#### **About the Presenter**

Dr. Kingston has 40 years' experience in clinical toxicology and pharmacology, poison control, product post-market surveillance, and drug and dietary supplement safety. In the area of Product Safety/Regulatory Policy he has helped shape national policy on a variety of critical issues related to product safety, including rules and regulations, and law interpretation by several federal agencies. He co-founded SafetyCall after holding top leadership roles in academia and the Minnesota regional Poison Center where he gained decades of critical care toxicology experience while practicing in a University-affiliated Level One Trauma Center. He also holds academic appointments at the Universities of Minnesota and Mississippi.