



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

June 27-28, 2019 | Hilton Baltimore Inner Harbor

### Regulatory Track: Workshop 3

3:00–4:30 p.m.

#### Enforcement Hot Topics: It's Not the 483, It's the Consumer

Presented by Mark Land, MS, RAC, President of [American Association of Homeopathic Pharmacists](#) and Vice President of Government & Regulatory Affairs, [Boiron USA](#)

FDA's draft guidance is a shift from a compliance policy guide to risk-based enforcement with a list of six areas of priority. This workshop will identify areas in which manufacturers and private labelers can properly understand the aims of a pharmaceutical quality system and reduce their risk through an analysis of warning letters, import alerts, inspection citations and recalls. The statistics will provide insight on the agency's enforcement approach and priorities. FTC activities will also be examined.

#### What You Will Learn:

- Quality systems best practices, checklists, and profiling to prepare for your next inspection.
- Post inspection programs reduce risk.
- FDA inspection trends (e.g., inspection frequency, observations vs enforcement, domestic vs international action).
- Where lie the hot topics: data integrity, analytical methods, process validation, adverse event reporting, non-self-limiting indications or supplier management.
- Cost of non-compliance.

#### About the Presenter

Mark Land, M.S., RAC, president of the American Association of Homeopathic Pharmacists, which represents the manufacturers of homeopathic medicines to the national regulators and legislators in Washington D.C. He is also the vice president of Government & Regulatory Affairs for Boiron USA, where he has worked in the homeopathic pharmaceutical industry for 39 years. Additionally, Mark volunteers as the Chairman Monograph Review Committee, [Homeopathic Pharmacopoeia Convention of the U.S.](#) His areas of interest and experience include: legal, regulatory, manufacturing, quality control and distribution of homeopathic drug products.