



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

June 27-28, 2019 | Hilton Baltimore Inner Harbor

### Quality Track: Workshop 1

10:15–11:45 a.m.

#### **Analytical Development Challenges in Homeopathy: Detect and Quantify Quality, and Toxicological Markers**

Presented by *Stéphanie Chanut, Pharmaceutical Development Laboratory Manager, [Boiron](#) (France)*

The most frequently cited GMP deficiency during homeopathic facility inspections in 2018 was 21 CFR 211.160(b): "lack of scientifically sound laboratory controls." This workshop will review the presenter's research with various analytical methods applied to homeopathic active ingredients and dosage forms. Examples will be provided using case studies of the detection of alkaloids and other characteristic constituents in tinctures, dilutions and finished products.

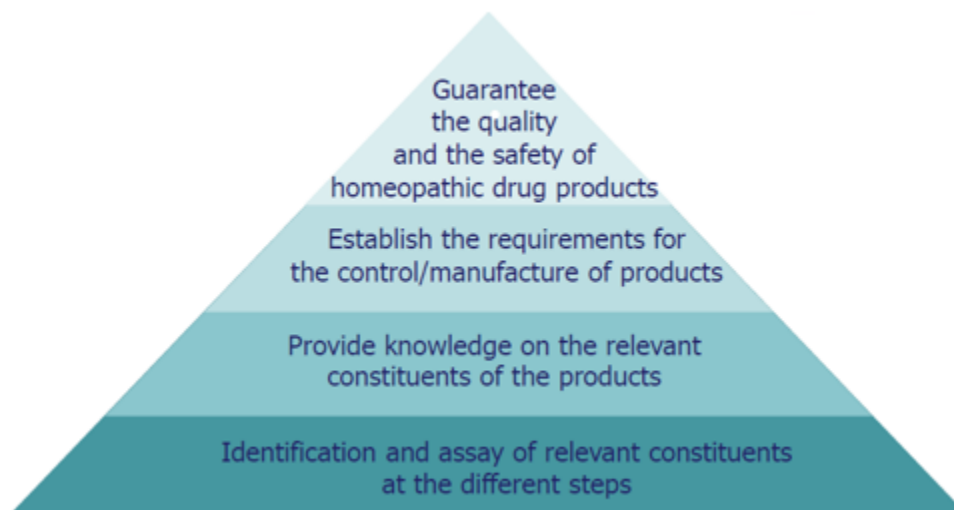
#### **What You Will Learn:**

- Regulatory background of homeopathic drug products.
- Manufacture technique for finished products and the purpose of the analytical development.
- Detection, identification and quantification of analytical markers in tinctures.
- Analytical techniques from tincture to dilutions and finished products.

#### **About the Presenter**

Now in her 13th year at Boiron, Stéphanie Chanut manages a team responsible for analytical development, stability studies, and liquid and gas chromatography set-up at Boiron. She began her career at Boiron as a Regulatory Affairs Manager Engineer before being promoted to coordinate and develop stability studies. She has managed a range of homeopathic medicines at the regulatory level (topical and sterile drugs), as well as monitored subcontractor activities and pharmacovigilance activities. Stephanie started her career at Sanofi Pasteur and then Merck Generics in technical regulatory affairs. In 2005, she earned her engineering degree in chemistry and biology from the National Institute of Applied Sciences in Lyon, France.

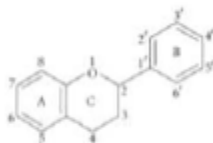
## Purpose of the Analytical Development



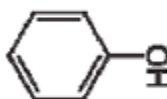
## Main Phytochemical Compound Families

### Alkaloids

### Flavonoids



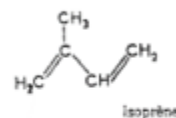
### Phenol acids



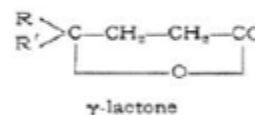
### Tanins



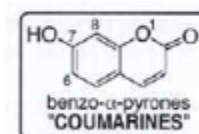
### Terpenic compounds



### Lactones



### Coumarins



### Quinones



This workshop will propose a development methodology to identify and quantify (if possible) quality and toxicological markers in the tincture and then in the dilutions and the finished products with examples of a gel and a syrup