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

June 27-28, 2019 | Hilton Baltimore Inner Harbor

Quality Track: Workshop 3
3:00–4:30 p.m.

Moves Toward FDA Requirements: Establishing Homeopathic Finished Product Specifications and Shelf Life
Presented by Fanny Guillot, Regulatory Affairs Officer, AMM (marketing authorization) Development Unit, Boiron (France)

Homeopathy is a singular drug product with singular challenges. Globally, regulatory officials are drawing upon successful marketing authorization requirements from different parts of the world. Fortunately, this convergence of different interpretations and viewpoints is creating a consistent manner helpful to all involved. Manufacturers and private labelers can also use global synergies to demonstrate quality and safety to U.S. health authorities. As FDA prepares to adopt its draft guidance, this workshop will show how the industry could use a multi-country approach to strike a balance between the analytical cost and quality assurance.

What You Will Learn:

- Regulatory framework for specifications and shelf life.
- Proposed approach through Europe for homeopathic dilutions and finished products.
- Establishing specifications for a finished product containing homeopathic dilutions: pharmacotechnical parameters.
- Transposition for stability evaluation of dilutions and finished products.
- A regulatory approach in the context of FDA's new dynamic to provide guarantees as regards quality of homeopathic finished products.

About the Presenter
As Boiron's regulatory affairs officer, Fanny Guillot has a global perspective of evaluating if products in a wide variety of therapeutic categories meet regulatory requirements for distribution in more than 50 countries. Specializing in regulatory requirements throughout the life cycle of health products, Fanny joined the global headquarters of Boiron two years ago. She holds a master's degree in Pharmacy from the Institute of Pharmaceutical and Biological Sciences in Lyon, France and a master's in Regulatory Health Engineering Regulatory Technological Affairs by apprenticeship through the Université Claude Bernard, also in Lyon.

Setting specifications of homeopathic finished products ensures the safety and the quality while running stability studies defines storage period.