



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

June 27-28, 2019 | Hilton Baltimore Inner Harbor

Safety Track: Workshop 2

1:00–2:30 p.m.

Part I: Principles of Toxicology

Presented by Matthew D. Reed, PhD, DABT, Fellow ATS, Principal, [Coelus LLC](#)

The Father of toxicology, Paracelsus said, “the dose makes the poison.” The scientific community, industry, and regulators apply these concepts to safety assessment of new products for human use and to industrial and environmental chemicals and mixtures that are/may become a part of our work force or daily environments. The FDA, EPA, and the international community have set precedents for methods of determining safe human exposure and dose levels. How do these precedents pertain to FDA's emphasis on certain botanicals with potentially toxic alkaloids? Matt's presentation will prepare you and your staff with the background and information necessary to understand and perform in-house confirmation of the HPUS first OTC attenuations in line with international assessment standards, so you can be certain your products are safe for sale to consumer.

What You Will Learn:

- Overview of risk assessment principles.
- Basic tenets of toxicology T-testing.
- Program design considerations.
 - General regulations and guidelines (pharmaceutical examples).
 - Species selection.
 - Specific chemical/product class/use.
- Study design considerations.
 - Specific design parameters.

About the Presenter

Matt Reed is the Principal and CEO of Coelus LLC where he facilitates full phase development of pharmaceutical IP and provides consulting services in toxicology, pharmacology, and hazard assessment. Dr. Reed is a pharmacologist, board certified toxicologist, ABT Board Member, and Fellow-Academy of Toxicology Sciences (ATS). He has more than 25 years' experience having successfully transitioned multiple R&D programs through regulatory registration milestones.