Elemental Impurities Testing 101:
Understanding the ICH Q3D and USP <232>/<233> Requirements

August 6, 2018
1:00-5:15 PM
Fluno Center, Madison, WI

Course description:

Over the last couple of years there have been significant changes in the regulatory requirements for elemental impurities testing for drugs and biologics. Understanding the requirements, how and when to implement the testing and setting appropriate specifications have continued to cause confusion within the industry. Companies continue to receive regulatory feedback/questions from the FDA during IND/NDA/BLA reviews resulting in potential delays to their developmental programs. This course will cover the specific requirements of the applicable guidances (ICH/USP/FDA) along with common challenges and pitfalls which companies have encountered. By better understanding the regulatory requirements you will be better equipped to avoid these potential pitfalls. This course will cover the following topics

- History of elemental impurity testing
- Comparison of ICH Q3D vs. USP <232> and <233>
- Risk assessment and gathering information from suppliers
- Analytical strategies and techniques
- Challenges associated with testing
- Case studies of testing implementation
- Specification settings: raw materials, components, API, Drug Product
- And *much* more!

Who should attend:

This course is intended for individuals needing a practical overview and understanding of the requirements for elemental impurities. It is intended for those responsible for implementing testing, setting speciation or responsible for working with vendors and suppliers to obtain the required information. It will benefit those in research and development, quality control, quality assurance, technical operations and regulatory affairs.

Contents:

12:30 pm Registration

1:00 pm **The basics of elemental impurities**

- History
- New Requirements
- FDA guidance
- Analytical Techniques

2:00 pm Break

2:15 pm **Risk Assessment Process**

- What is the risk assessment?
- What data is required?
- What are the method requirements?

3:15 pm Break

3:30 pm **Control of Impurities**

- Specification setting
- Calculations
- Analytical method requirements for routine testing

4:30 pm Break

4:45 pm **Case Studies**

5:00 pm Open Discussion

5:15 pm Adjourn Pre-Conference Workshop

Instructor: Wayland Rushing, Ph.D.
Director, Scientific Affairs
EAG Laboratories, Columbia, MO

Fee: $175

Register: https://ce.pharmacy.wisc.edu/pd/pharmaceuticalanalysisconf/