November 2 - 3, 2017
USP Meeting Center
Rockville, Maryland

PQRI/USP Workshop on ICH Q3D Elemental Impurities Requirements - Recent Experience and Plans for Full Implementation in 2018

Key Speakers from FDA, USP and International Regulatory Authorities

Workshop Description

The implementation of the ICH Q3D guideline will go into full effect in the United States and Europe in 2018 for all products. The Q3D guideline has been applied to new drug applications in the United States and Europe since June 1, 2016. This workshop will provide an overview of the first sixteen (16) months of compliance experience and will review ongoing work throughout industry to resolve challenges involved in global implementation of the Elemental Impurities (EI) guidelines and standards. Specific topics will include the following:

- Update on Recent US/EU/JP Regulatory Guidance, Compendial Chapters and further ICH EI Initiatives
- Company and regulator experience with implementation for new drug applications since June 2016
- Implementation of Q3D requirements for OTC and existing Prescription Drugs in January 2018 – Challenges and Expectations
- Acceptable Risk Assessment Strategies
- Global Developments for EI Requirements
- PQRI Phase 2 Collaborative study - outcomes and recommendations
- Outstanding Analytical Challenges

This workshop will include global experts from ICH Q3D IWG, industry, regulatory authorities, pharmacopeias, and academia who are intimately involved in this area.

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Registration is now open. Early bird rates available until August 1, 2017.

Register at: www.signmeup.com/120298.

More information at the PQRI website at: www.pqri.org.

Questions? Contact the PQRI Secretariat at: PQRISecretariat@pqri.org.