Global Expertise
Trusted Standards
Improved Health

U.S. Pharmacopeial Convention

The USP Excipients Stakeholder Forum
Meeting #1
June 7, 2013

Elemental Impurities Update

Roger L. Williams, M.D.
CEO and Chair, Council of Experts

Elemental Impurities Implementation Update

- General Chapters <232> and <233> became official February 1, 2013; meeting the requirements of the general chapters will be through a General Notices provision applied to drug product monographs
- The General Notices provision (5.60.30) proposed in *Pharmacopoeial Forum* 39(1) has been deferred and the original implementation date of May 1, 2014 will ***not*** become official
- A new implementation date has not yet been established
- The Elemental Impurities Expert Panel reporting to the Chemical Analysis Expert Committee will revise General Chapter <232> Elemental Impurities—Limits to align with the ICH Q3D Step 2 limits. Other editorial changes will be made.
- USP has formed a non-standards-setting Advisory Group to address implementation issues

Advisory Group

- The EVP-CEO appoints advisory bodies “to advance the work of the Council of Experts and the Convention and provide advice to staff on policy matters. “
- The Elemental Impurities Implementation Advisory Group members comprise:
  - Representatives of key trade organizations that submitted comments to USP on the implementation of the General Chapters
  - Three FDA representatives
  - The rapporteurs of the ICH Q3D Expert Working Group
  - The chair of USP’s Toxicology Expert Committee
- Will consider implementation recommendations to USP as it relates to the General Notices provision.
- Expectation that it will conclude its work expeditiously so that a new implementation date can be established.

Advisory Group Areas of Focus

- Working groups have been formed to address the following areas of focus:
  - Implementation requirements related to <232> and <233>
  - The omission of <231>
  - Special impact on manufacturers

- USP will keep stakeholders informed through web postings on the Elemental Impurities Key Issues page, including summaries of the Advisory Group's deliberations.

Thank You