4th PQRI Workshop on ICH Q3D Elemental Impurities Requirements
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An Update on USP Element Specific Chapters

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Session Description and Objectives

- This presentation will highlight the current status of elemental impurities. It will also include information regarding the EI sub-committee's efforts regarding element-specific chapters
- Understand where in the process things are with regard to elemental impurities and element-specific chapters.

Biography and Contact Information

- Nancy led the atomic spectroscopy laboratory at Bristol-Myers Squibb for almost 30 years.
- Nancy has served as the chair of the USP Chemical Analysis Expert Committee since 2015.
- She is the chair of the USP Elemental Impurities Expert Panel
- She is currently a consultant with Owasso Pharmacon LLC
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USP <232>--Elemental Impurities

Features of <232>

- applies to drug products
  - options to test components and contributions from processing equipment, etc. OR test drug product when testing is required
- risk-based approach
  - generally not required to test everything for all potential elements
  - develop a risk assessment

Implemented for ALL drug products in January 2018

USP Element-Specific Chapters and Elemental Impurities

- USP has several chapters that address specific elements
  - Aluminum, Arsenic, Selenium, Mercury, Lead
- With the exception of Al; As, Se, Hg and Pb are all elements that are potentially needed for risk assessment for USP <232>
- How to reconcile method of analysis from <233> (used with <232>) and element-specific chapters?

Stimuli to the Revision Process Article

- Article published to generate industry discussion regarding element-specific chapters.
- Proposal was to remove those and rely on elemental impurities risk assessment (per USP <232>) and analytical procedure (USP <233>)
- Although industry did not wish to require that excipients be required to comply with USP <232>/ICH Q3D, they did not wish to have these chapters removed, wishing, instead to retain required testing for elements that would otherwise be covered by USP <232>/ICH Q3D

Element-Specific Chapters

- Revision to the element-specific chapters to permit testing procedure used in USP <233>
- Can still use “old” testing procedures, per the individual chapters

Small Molecules Approach

- Removing all tests for elements that are part of USP <232>/ICH Q3D elemental impurities list from organic drug substance monographs

QUESTIONS?

- Thank you for your kind attention
- Thank you to Kahkashan Zaidi for valuable input