

FDA's Update on Elemental Impurities According to the new ICH Q3D and USP 232/233 Guidelines - Are you ready?

Duration: 90 Minutes

New, dramatically different requirements for elemental impurities will soon be introduced for most pharmaceutical products. These requirements cover more metals and require lower limits than the antiquated Heavy Metals test. Additionally, the analytical technique, ICP-MS, is much more challenging. By attending this course you will learn about the new requirements and also about using risk assessment to minimize unnecessary testing and meet FDA expectations.



Instructor: Gregory Martin
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Live Session for one participant - \$250.00 | Recorded Session - \$375.00 | Training CD - \$500.00 | Corporate Live Max 10 Participants - \$1250.00 | Live + Recorded webinar - \$500.00 | Live + Training CD - \$625.00

Objectives of the Presentation

- How the new FDA Guidance on Elemental Impurities is related to ICH Q3D and USP Chapters 232 and 233
- What drug products are within the scope of the guidance
- Which classes of drug products need to comply with ICH Q3D and which with USP 232/233
- How risk assessment influences what testing is required
- What documentation related to control of elemental impurities is expected by FDA
- Which procedures can be used to demonstrate compliance
- How methods should be validated

Why Should you Attend

FDA has issued a Draft Guidance on Elemental Impurities in Drug Products, which addresses ICH Q3D and USP General Chapters 232 and 233 on this topic. The Guidance makes recommendations on how to submit NDAs or ANDAs for non-compendial drug products, and how manufacturers of compendial drug products can comply with the new requirements. The similarities and differences between ICH Q3D and USP 232/233 are discussed, and recommendations are made for different categories of drug products, including compendial and non-compendial, and those approved under an NDA/ANDA or not approved under an NDA/ANDA. A risk-based approach to the control of elemental impurities is advocated, which informs which elements are likely to be present and what controls are appropriate. The guidance also addresses validation of analytical procedures and early adoption of the standards.

Areas Covered

- Elemental Impurities: The case for Change
- Overview of Guidance Documents: FDA, ICH Q3D, USP 232/233
- Scope of the guidances
- Risk Assessment
- FDA Recommendations
- Controls and Documentation
- Analytical Procedures and Validation
- What you should be doing now

Who will Benefit

Pharmaceutical RandD and QC chemists and their managers; Regulatory Affairs personnel, including those responsible for filing NDAs and ANDAs or other drug products and those responsible for Annual Reports and updating analytical methods and specifications. Individuals at Contract Manufacturing and Contract Laboratory facilities should also attend.

Instructor Profile:

Greg Martin is the President of Complectors Consulting, which provides consulting and training in the area of Pharmaceutical Analytical Chemistry. Mr. Martin has over 25 years experience in the pharmaceutical industry and was the Director of Pharmaceutical Analytical Chemistry (RandD) for a major PhRMA company for a number of years. In addition, he has volunteered for the USP for over 10 years, and currently serves on the General Chapters - Chemical Analysis Expert Committee, and serves on Expert Panels on Validation and Verification, Residual Solvents and Use of Enzymes for Dissolution Testing of Gelatin Capsules. He has particular interest in QbD/Lean approaches to dissolution testing, impurity methods, method lifecycle (development/validation/transfer) and instrument qualification, and is passionate about using good science and sound logic to achieve high quality results, consistent with cGMPs, while minimizing resources. Mr. Martin is the author of several papers in the areas of dissolution and analytical method validation, and was the past chair of the AAPS In Vitro Release and Dissolution Testing Focus Group.