Alternatives for Content Uniformity Acceptance Criteria and Stratified Sampling

Moderators:
- Siva Vaithiyalingam, Teva Pharmaceuticals
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Session Outline

• **Background**: Uniformity of dosage units (UDU) can be demonstrated by Content Uniformity (CU) or Weight Variation (WV) based on the individual drug products. The method to ensure CU in the finished dosage forms is of particular interest to all stakeholders given that it can be a high-risk CQA for products with low dose or narrow therapeutic index.

• **Challenges**: Draft *Guidance for Industry Powder Blends and Finished Dosage Units – Stratified In-process Dosage Unit Sampling and Assessment* was withdrawn in 2013 since specific sections (e.g., Section V and VII) no longer reflected the Agency’s current thinking. USP <905> *Uniformity of Dosage Units* is intended for conformance to defined samples without factoring in a statistical sampling plan.
Session Outline

• Topic I: Uniformity of Dosage Unit USP <905> Maintaining Relevance
  
  Jon Clark, USP

• Topic II: Recommendation for the Assessment of Blend and Content Uniformity: Modern Approaches to Sampling and Testing
  
  James Drennen, Duquesne University

• Topic III: Statistical Considerations for Establishing AC for CU and Stratified Sampling
  
  Alex Viehmann, OS/OPQ/CDER/FDA

• Panel Discussion
Panel Discussion

To the panel:

1. In your opinion, what are the current challenges/barriers in selecting proper sampling planning and defining CU acceptance criteria?

2. What can be the CU acceptance criteria for 100% unit testing (e.g., using PAT during continuous manufacturing)?

To the audience:

What (stratified) sampling method(s) and CU acceptance criteria have you recently adopted and have been approved by health authorities?