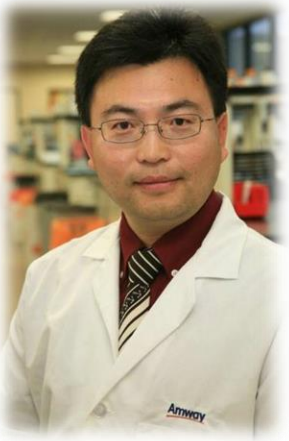
Quality by Design (QbD) in Analytical Method Development

Sample Preparation Challenges and Solutions



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The QbD concept has been widely adopted by pharmaceutical industries to establish product target profile, define product design criteria, develop the critical quality attributes and quality control strategy.

An analytical method development typically includes sample preparation, instrument measurement, data analysis and result reporting.

Sample preparation is a very critical step in quantitative analytical method, because it determines method accuracy, precision, recovery, sensitivity, stability and reproducibility.

In this session, we will discuss different challenges in sample preparation, including analyte stability, recovery, and automation, understand their impacts on the analytical results, and recommend best practices for analytical method development.

No	Presenter	Title
		Introduction
1	Xun Yan	Efficiency of extraction procedure and analyte stability in vitamin A and E analysis
2	Michael S. Young	Techniques and Tools for Simplified Sample Preparation
3	Aihua Liu	Analyte Stability Issues during Sample Preparation: Recommendations for the Best Practices
4	Walt Brandl	Sample preparation techniques for encapsulated analytes
5	Kai Zhang	Evaluation of automated sample preparation for mycotoxin analysis
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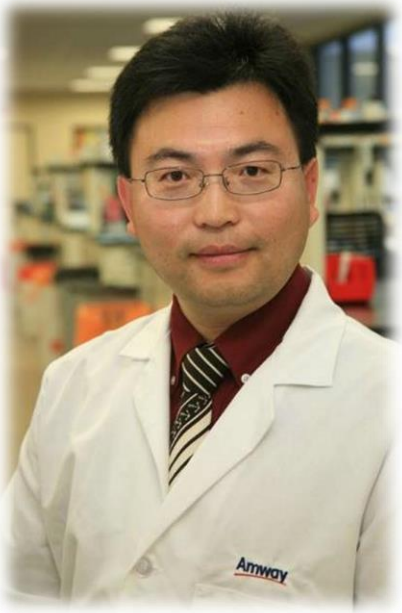
Efficiency of extraction procedure and analyte stability in vitamin A and E analysis



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Dr. Xun Yan is a principle scientist in chemistry lab at Amway RD. He has been working for 10+ years on method development for nutrition and cosmetic products. The analyte targets include carbohydrates, lipids, polyphenolics, and Vitamin A/E/C, for example. He is specialized in stability analysis and method trouble shooting.

Techniques and Tools for Simplified Sample Preparation

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Dr. Michael S. Young received his Ph.D. in analytical chemistry and had worked at Waters Corporation for 25 years as a Principal Analytical Chemist for developing LC-MS and GC-MS applications using solid-phase extraction (SPE), and other sample preparation methodologies. Dr. Young will soon be joining Cambridge Polymer Group as a senior research analytical chemist.

Analyte Stability Issues during Sample Preparation: Recommendations for the Best Practices

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Dr. Aihua Liu is R&D director at Dyad Labs. She holds a PhD in Pharmacognosy, and has more than 15 years of experience in analytical method development, method validation, and sample analysis under GLP/cGMP regulation using UPLC/HPLC, MS, GC and FLD. She has authored more than 30 peer-reviewed scientific articles and presented over 30 posters in different international scientific conferences like AOAC, ASMS, AAPS and ICBS et al.

Sample preparation techniques for encapsulated analytes

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Dr. Walt Brandl has been involved in commercial analytical labs for over thirty-five years, having held positions in quality, research and development and general laboratory management. He is currently the Regional Director of Chemistry in North America for Merieux NutriSciences. One of his main responsivities is method development and he is currently working with a number of clients on optimizing methods for the determination of encapsulated vitamins. In his non-work life he is involved in coaching rugby and has plans to cruise the scenic British Columbia coast.

Evaluation of automated sample preparation for mycotoxin analysis

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Dr. Kai Zhang is a research chemist at Food and Drug Administration, A Center for Food Safety and Applied Nutrition. As an expert on mycotoxin analysis in foods. Dr. Zhang has been recognized for modernizing FDA's mycotoxin analysis by evaluating, developing and implementing LC-MS techniques to support the FDA mission for enforcing regulatory levels established for toxic mycotoxins in foods. Dr. Zhang's current research interests include developing chromatographic and mass spectrometric methods for mycotoxin analysis in foods and exploring automation technologies for sample preparation.