Residual Solvents: Take Advantage of the New Flexibility in Revised USP <467>

Description: Live Webinar:
18 March 2016: 1:00 PM EST

Course Description:

This course provides participants with an understanding of the regulatory landscape for residual solvents requirements and provides strategies and recommendations to minimize the amount of effort needed to comply. We address options such as whether to test raw materials or drug products, whether to use USP or alternate testing methods, when to screen for all solvents and when to test for specific solvents. Significant resources can be saved by reduced testing, and we discuss the steps necessary to do this successfully. We’ll explain how new information on verification or validation of analytical procedures clarifies what must be done. We also talk about some of the unresolved challenges related to residual solvents compliance. There will ample opportunity for questions and discussion.

Course Objective:

Upon completion of this course the learner should be able to:

1. Understand the requirements for residual solvents addressed in ICH, USP, EP and JP.
2. Take advantage of the flexibility introduced in the revisions to USP <467>
3. Utilize strategies to minimize the testing and resources required to meet the requirements
4. Verify the USP procedure (or validate alternatives) in accordance with expectations

Target Audience:

- Chemists or managers responsible for testing or release of drug substances.
- Excipients or drug products for which residual solvents must be controlled.
- Quality Assurance and Regulatory Affairs.
- CMC personnel responsible for reviewing associated data or filings.

Contents: Course Outline:

- Regulatory Landscape for Residual Solvents: ICH, USP, EP and JP
- Revision to USP <467>: improved clarity and flexibility
- Discussion on various approaches to compliance, and how to minimize resources
- Unresolved issues: solvents with poor volatility or not yet addressed
- Questions and Discussion


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