Michael Klein is a Brand Manager for HPLC & UHPLC products at Phenomenex, who specializes in the Pharmaceutical and Biopharmaceutical industries. This article was published in Laboratory Focus on December 10.

Effective August 2014, the United States Pharmacopoeia and the National Formulary (USP-NF) published the latest revision to General Chapter <621> on Chromatography that further clarifies what “allowable adjustments” can be made to USP methods without having to revalidate these methods. In other words, any of these changes made to a particular method would still meet the original system suitability requirements.

Understanding this latest revision is critical to improving productivity and cutting costs in any lab environment, yet it can be overwhelming to many less experienced chromatographers.

Generally these USP monographs were created for older generic drugs that are still manufactured and sold worldwide, and many of these methods were developed on older materials and are time-consuming to run. To increase productivity in the lab, improvements must be made to these methods in order to reduce these lengthy run times while still maintaining the system suitability requirements defined by the monograph.
Allowable Adjustments to Pharmacopoeia Methods: Simplified Version

>> Read the full article HERE

Related resources:

• Kinetex Column Selection for European Pharmacopoeia Methods
• Compendial Methods: Determination of Impurities and Related Substances
• Allowable Adjustments to Pharmacopoeia Methods
• Size Exclusion Chromatography Method Optimization Using the European Pharmacopoeia for Insulin Fibrils
• Understanding the Revisions to USP Monograph <467>: Residual Solvents
• Revised USP Chapter 467 and its Applications to Excipient Qualification and Testing

Share with friends and coworkers:

• Click to email this to a friend (Opens in new window)