Stimuli Article on Lifecycle Management of Analytical Procedures Posted for Comment

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Expert Committee: General Chapters—Physical Analysis

The members of the USP Validation and Verification Expert Panel, working under the direction of the General Chapters—Physical Analysis Expert Committee, are posting a Stimuli article to present their current thinking on lifecycle management of analytical procedures. The Stimuli is being presented in advance of its publication in Pharmacopeial Forum 39(6) to allow additional time for public review and comment.

In the Stimuli article, <u>Lifecycle Management of Analytical Procedures: Method Development, Procedure Performance Qualification, and Procedure Performance Verification</u>, the Expert panel suggests that the traditional approaches to validation, transfer, and verification should be integrated into the analytical procedure lifecycle process rather than be viewed as separate entities. This applies the modern concept of a lifecycle model to analytical procedures. This stimuli article should be considered as a roadmap for new validation standards that will be developed and presented over the course of the next couple of years.

Your comments and suggestions are desired. Comments will be accepted until January 31, 2014, the end of the comment period for Pharmacopeial Forum 39(6).

Should you have any questions or comments, please contact Horacio N. Pappa, Ph.D., CQE, Principal Scientific Liaison (hp@usp.org or 301 816-8319).