



U.S. Pharmacopeia
The Standard of Quality™

Performance Based Monographs

Presentation: Quality of Manufactured Medicines – New Compendial Initiatives Performance Based Monographs

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The ability of pharmaceutical companies to introduce improved analytical methodology to pharmaceutical products is hampered by the challenges of meeting the diverse requirements of all the various pharmacopeial and regulatory bodies. This talk will provide some example case studies to illustrate these challenges and highlight how the concept of performance based monographs may help address some of the current barriers to improvement.

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