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USP monograph modernization-procedure review and development

Donald Min
United States Pharmacopeial Convention, USA

Public and regulatory expectation is that all pharmaceutical products, including over-the-counter (OTC) products and legacy prescription (Rx) products, will be safe and of high quality and those pharmacopeial requirements in USP-NF are adequate to ensure this level of quality. As USP global initiative to modernize existing monographs across all compendia, objectives and criteria for the monograph modernization are discussed. Identification, assay, organic impurities and other tests in the USP monograph are re-assessed and revised with modern analytical techniques. Orthogonal identification and organic impurities test with specified impurities based on HPLC/UHPLC are emphasized in the modernized monograph. Multi-sourced sample procurements and method development and validation by USP internal laboratories are utilized to fulfill the test procedures and additional specifications in the monograph, along with case studies for the critical steps/challenges of the procedure developments. With the modernized monographs and the support from FDA, the use of the test procedures in the monographs are important to strengthen the appropriate control of impurities in API, in excipients, and in drug products to improve the quality of the pharmaceutical products, to protect public health, and to achieve USP mission of providing high-quality public standards.

Biography

Donald Min is a Senior Scientific Liaison in USP. His responsibilities include monograph development and review, in particular the chemical medicine monograph modernization initiated by USP laboratories. After completed his PhD at Montana State University and post doc training at University of Missouri, he had spent over 20 years in analytical method development/validation and solid-state characterization in support of pharmaceutical R&D and quality operations. Prior to joining USP, he was manager for global quality support and technical lead for compendial compliance, at Schering-Plough/Merck.

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