

The International Harmonization of the Compendial Microbial Limits Tests— A Cautionary Tale of Compendial Participation

By **Scott Sutton, Ph.D.** May 31, 2013 10:17 am EDT

The international harmonization of the United States Pharmacopeia (USP), Japanese Pharmacopeia (JP), and the European Pharmacopoeia (EP, Pharm Eur) Microbial Limits Tests is now finalized. USP chapters involved in this harmonization include <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests; <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms; and <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances For Pharmaceutical Use Changes to...

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