

## Harmonized Microbial Limits Validation Deadline Imminent

LANCASTER, Pa., December 15, 2008—As the first of three compendia deadlines nears, Lancaster Laboratories provides the technical and regulatory expertise to assist the industry in achieving compliance with the new Harmonized Microbial Limits methods. In an effort to harmonize microbiological test methods between the major compendia, the United States (USP), European (EP) and Japanese (JP) Pharmacopoeias have agreed on new methods for microbial enumeration tests and tests for specified microorganisms. Use of the new methods will be required beginning January 1, 2009, for those who reference the EP methods (2.6.12 and 2.6.13), April 1, 2009, for the JP methods (4.05) and May 1, 2009, for the USP methods ( and ).

“We’ve been offering the harmonized methods for two years and have completed more than 200 product validations for more than 50 different clients,” says Mike Yunginger, manager of Non-Sterile Products at Lancaster Laboratories. Although new validations are needed for existing formulations, Yunginger explains that the change is beneficial because one method will now meet the requirements of any agency that recognizes either USP, EP or JP. He encourages clients to review their list of products that are currently validated and call their Lancaster Labs client service representative to make arrangements for revalidation of any products that will continue to require microbial limits testing after the effective dates for the harmonized methods. Having the validation completed prior to the effective dates for the methods will allow a seamless transition from the individual methods to the harmonized methods.

Lancaster Laboratories has ranked #1 Laboratory of Choice in Pharmaceutical Technology surveys consecutively since 1996 based on scientific and regulatory expertise, meeting project deadlines, customer service and price. And the company’s Harmonized Microbial Limits Validation program further enhances customer’s service experience.

The global leader in Pharmaceutical/Biopharmaceutical testing services, Lancaster Laboratories provides innovative and timely scientific solutions that enable customers to better manage the drug development process. Lancaster Laboratories Europe/Microchem in Ireland further broadens global customer service options.