

## Lancaster Laboratories' launches new mycoplasma USP assay; harmonizes with EP Guidelines

LANCASTER, Pa., November 17, 2010—Lancaster Laboratories, a global leader in biological safety testing, has introduced a new cGMP compliant mycoplasma assay, harmonizing both United States Pharmacopeia (USP) Chapter monograph and European Pharmacopoeia Chapter 2.6.7 guidelines.

With the USP's recently published Chapter Mycoplasma Tests, biopharmaceutical companies performing mycoplasma testing need to comply with this new guideline, effective October 1, 2010. Chapter was intended to bring requirements in the U.S. closer to those outlined in the EP and to further harmonize mycoplasma testing by bringing greater alignment in the monographs.

Mycoplasma contamination of cell culture represents a significant issue in the development and production of biologics. Mycoplasma contamination events can lead to altered physiological properties of cells, leading to reduced or altered cellular products and perhaps unsafe biopharmaceuticals. Thus, testing for the presence of mycoplasma contamination in development and manufacturing is a requirement by the worldwide regulatory agencies, including the United States, Europe and Japan. Guidance for this testing is provided in the FDA 1993 Points to Consider (PTC), European Pharmacopoeia Chapter 2.6.7 Mycoplasmas, and the Japanese Pharmacopeia XV,14. Mycoplasma Testing.

"By offering validated assays performed in compliance with FDA, PTC, EP and USP, we are ensuring compliance for mycoplasma screening of cell lines and biological products for our global customers." says Dr. Jeri Ann Boose, Lancaster Laboratories' director of biopharmaceutical services.

Features of Lancaster Laboratories Mycoplasma testing program include:

- Fully traceable, characterized and qualified positive control strains
- Formalized analyst training program, including required proficiency assessments using blind samples
- Limited access laboratories that are pressure-controlled, HEPA-filtered, and operate on independent air handling systems to prevent cross contamination
- Separate laboratories for testing of client test articles and handling of positive control strains, including a unidirectional workflow that ensures handling of test articles prior to manipulating positive controls on each working day
- Assays performed in strict compliance with cGMPs
- Mycoplasma testing to qualify each assay for each test article
- Support for mycoplasma clearance studies, including consultation and study design
- Access to Lancaster Labs' proprietary LabAccess system, allowing 24/7 easy access to study information, final reports and actual raw study data

Founded in 1961, Lancaster Laboratories is the global leader in pharmaceutical and biopharmaceutical laboratory services, providing innovative and timely scientific solutions that enable customers to better manage the drug development process. Visit [lancasterlabpharm.com](http://lancasterlabpharm.com) and discover why customers rank Lancaster Laboratories #1.