104 Gold Street
Agawam, MA
1-800-631-1680
www.microtestlabs.com

# CLEANING-DISINFECTION-STERILIZATION OF REUSABLE MEDICAL DEVICES

## Join us for a "Lunch and Learn" Seminar.

We'll discuss the most current regulatory expectations.

**When:** December 04, 2013 9:00 a.m. – 1:00 p.m.

**Where:** The Conference Center at Waltham Woods
860 Winter Street, Waltham, MA 02451

**What:** Validation of Reusable Medical Devices is in the forefront of FDA's efforts to ensure patient safety. Requirements for cleaning, disinfection and sterilization of reusable devices are constantly changing. This leaves manufacturers with a dilemma as to the methods to use and the end points to test for. Knowledge of current regulatory expectations may increase the chances of submissions being accepted without requiring additional testing.

**Fees:** $149 (payment required in advance)

## Topics To Be Discussed Include:

- Discussion of FDA's draft guidance for Industry and FDA staff "Processing/Preprocessing Medical Devices in Healthcare settings."
- Methods used for cleaning validation of reusable devices
- Methods for disinfection of reusable devices
- Methods for sterilization of reusable devices
- Testing requirements
- Detailed discussion of endpoints for cleaning validation

## Speakers:

- Philip Nosel, Supervisor – Reusable Medical Devices
- Deborah Ensign, Supervisor – R&D Laboratory

For more information or to RSVP, contact 1-800-631-1680 X192 or jadamski@microtestlabs.com.

# *Cleaning-Disinfection-Sterilization of Reusable Medical Devices Seminar Speakers*

## *Phillip Nosel*

Supervisor – Reusable Medical Devices

Phil has over 20 years' experience in the laboratory, spending the last four (4) years in the Analytical Chemistry department at Microtest with three (3) years previously in the Quality Assurance department at Microtest. Phil holds a BS degree in Chemistry and an MS degree in Biochemistry. Prior to joining Microtest Phil worked as a chemist and QA Analyst at various companies supporting manufacturing, R&D, and QC. Phil is a member of the American Chemical Society and AAMI Committee WG84, Endoscope Reprocessing. Phil is the author of the Management Brief "Automatic Washer Validation for Medical Devices" available at www.microtestlabs.com. Phil's lab routinely performs cleaning validations on reusable and one-time use medical devices using quantitative endpoints.

## *Deborah Ensign*

Supervisor – R&D Laboratory

Deb has over 20 years' experience in regulatory microbiology and contract laboratory operations. Deb supervises Microtest's Specialized Microbiology department which routinely performs disinfectant qualifications, USP <61>, <62> and <81>, as well as filter challenges and phage testing. She holds a Bachelor of Arts degree in Microbiology and has been a nationally registered microbiologist for over fifteen (15) years. Deb serves as a resource for USP testing and reusable device disinfection and sterilization testing. She is a co-author of the Management Brief "The Background Behind Disinfection Qualifications" as well as the author of the white paper "Six Steps to Qualifying Disinfectants" published in *Contract Pharma*. Both are available at www.microtestlabs.com.

Microtest

# *CLEANING-DISINFECTION-STERILIZATION OF REUSABLE MEDICAL DEVICES*

## *Wednesday, December 04th, 2013*

### *REGISTRATION FORM*

Last Name: _____First Name: _____

Title: _____Organization: _____

Mailing Address: _____

Telephone #: _____Email: _____

**Fee: $149.00 Payment required in advance.**

This fee includes breakfast, snacks and refreshments, lunch and workshop handouts.

| *Additional Attendees* | | | |
|---|---|---|---|
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| Last Name | First Name | Title | Email Address |
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*Payment Information:* Check, Credit Card or Money Order
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Confirmation of registration will be sent via email.
Cancellation Policy: Your notice of cancellation must be received in writing 10 working days prior to the seminar date.