



Environmental Monitoring in Non-Aseptic Fill Areas Manufacturing / Quality SIG PLUS!

Date: 2/4/2010

Time:

Registration: 7:30 am - 8:00 am

Program: 8:00 am - 9:30 am

Event Description

The increased prevalence of combination devices has heightened regulatory scrutiny of medical devices, which in turn has increased implementation of process controls by device manufacturers and suppliers. Because many medical devices are terminally sterilized, it is important to minimize bioburden levels. Environmental control is a critical system that can have a direct impact on product bioburden. Environmental monitoring is performed to demonstrate the environmental controls are functioning properly. Although guidance documents exist for environmental monitoring of aseptic manufacturing areas, there is little guidance for non-aseptic manufacturing areas. This course will provide information to help establish an appropriate environmental monitoring program.

Pace Analytical Life Sciences is a full service contract analytical testing laboratory providing chemistry and microbiology testing services to the pharmaceutical and medical device industries. Services include methods development/validation, raw material testing, stability testing and storage, product release testing, chemical characterization and residual chemical analysis. Pace Analytical Life Sciences operates two laboratories, one located in Oakdale, MN and the other in San German, Puerto Rico. Pace Analytical Life Sciences is FDA and DEA registered and ISO/IES 17025 accredited.

Who should attend

QC and R&D Microbiologists, QC and R& D Managers, Quality Managers, Regulatory Affairs, and Senior Management

Information / skills to take away from course

Environmental monitoring is a valuable tool that provides assurance that environmental control systems are operating properly. Although numerous guidelines are in place for environmental monitoring in manufacturing areas used for aseptic manufacturing, little guidance is available for non-aseptic fill areas. A properly designed environmental monitoring provides allows for response to adverse conditions before product quality is affected. A risk-based approach will help establish an environmental monitoring program that provides the balance between costly compliance to standards that are not directly applicable to the process and generation of meaningful data.

Speakers

Angela A. Strantz, Ph.D., Director of Microbiology, Pace Analytical Life Sciences - Oakdale Location

Angela Strantz is the Director of Microbiology for Pace Analytical Life Sciences. Angela has worked in the Medical Device and Pharmaceutical industries for more than 15 years. She has extensive experience with microbiological testing associated with terminally sterilized, aseptically filled, and non-sterile products, including sterilization process validation, quality control testing, water system monitoring and environmental monitoring. Angela routinely presents *The Principles of Sterilization* as part of the FDA's Industrial Sterilization Course for inspectors and review personnel. She is member of the Parenteral Drug Association (PDA) and the Association for the Advancement of Medical Instrumentation (AAMI).

Topics

The following topics will be addressed:

- Manufacturing / Quality

Location

Pace Analytical Life Sciences - Oakdale Location
1311 Helmo Avenue North
Oakdale, MN 55128