Microbiological Control and Validation

This class is specifically designed to teach employees basic microbiological concepts, terminology, and regulatory expectations. It will also introduce them to the current requirements for microbiological recovery methods validation. This class will be applicable to everyday tasks performed within the microbiology laboratories and will be useful to employees responsible for understanding, interpreting and reviewing microbiological testing data. Employees will leave with a basic understanding of how organisms enter controlled environments, what it takes to reduce the number of organisms once contamination occurs, how to prevent contamination in the first place, and the work necessary to validate microbial recovery methods.

Who Should Attend: Microbiology lab technicians and supervisors and other employees responsible for understanding, interpreting and reviewing microbiological testing data.

Class Length: 1 ½ days

Maximum Class Size: 20

Course Prerequisites: None

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- General Microbiological principles including: microbial growth requirements, sources of common microorganisms, types of organisms found on people and in the environment
- The most common sources of microbial contamination and how to eliminate organisms once they have been introduced to an environment
- The basics of Aseptic Technique
- The FDA's expectation of cleanliness and monitoring for the controlled environments that the employees work in
- The current methods for microbial identification
- How to interpret data collected during microbial testing and how to identify trends when reviewing the data
- The current regulatory requirements for microbiological methods validation.
- The requirements for validation: VMP, IQ, OQ and PQ protocols
- The support systems required to maintain a validated system

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