COBBLESTONE

COURSE ID 3086

NEW!

Microbiology for the non-Microbiologist

Appropriate as a GMP Microbiological Refresher

DIRECTED BY

Barry Friedman Ph.D. — Senior Consultant in Biotechnology, Regulatory Compliance, Microbiology and Aseptic Processing

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Introduction to Industrial Microbiology
- Definitions Commonly Used in Microbiology
- Common Contaminants Based Upon USP <60> and <62> and In-House Microorganisms
- Environmental Contamination and What it Means to You
- Cross Contamination and What it Means to You
- Environmental Testing and Associated Challenges
- Management of Your Environmental/Water Utility Systems

about the course

With the increasing number of Regulatory Actions throughout North America to include Form FDA 483s and Warning Letters for both Active Pharmaceutical Ingredients (APIs) and finished product, it has become increasingly important for companies and individuals manufacturing both non-sterile and sterile final products, to have a basic understanding of microbiology -- regardless of the department in which they work. Every individual within varying departments from Facilities to Manufacturing to Quality Control should understand the basics of microbiology and the issues that non-compliance can create. Recently, a large multi-national pharmaceutical company was cited for the second time by the FDA for not determining that mold was growing on the "clean side" of the HEPA filters in an ISO Class 5 environment after it had been identified by mechanics several years previously.

In addition, a Form FDA 483 (January 2011) which was subsequently followed by an extensive recall (January 2011), a seizure, and ultimately a Consent Decree for a manufacturer of non-sterile and sterile alcohol prep pads, swabs, and swabsticks, illustrate the importance of having knowledgeable personnel regarding microbiological procedures within your manufacturing and laboratories facilities. This facility received multiple observations for not providing its personnel with adequate microbiological training and ultimately closed.

The objective of this 90-minute accredited webinar is to provide for the non-microbiologist an introduction and background to enable this individual to understand the basics of microbiology, as well as provide to the microbiologist (who may have moved on to other areas) a refresher course which addresses selected issues and answers facing those that may have microbiological concerns within their facilities. Plan to bring a cross-functional group of your personnel to attend this invaluable seminar.

who should attend

This course is intended for all scientists and technologists interested in developing a basic understanding or refresher of the basics of microbiology and the ramifications of non-compliance.

The material will be presented in such a way as to be a value to a varying level of expertise. This course will especially benefit those in:

• Facilities	• Validation
• Manufacturing	• Meteorology
• Quality Assurance	• R & D
• Regulatory Compliance	• Project Management
• Quality Control	• Microbiology

learning objectives

Upon completion of this course, you will be able to:

- Outline introductory-level concepts and definitions in Microbiology
- Identify Common Contaminants Based upon USP 60 & 62
- Examine Cross Contamination within a Manufacturing Facility
- Explain Environmental Testing and Associated Challenges
- Summarize the Management of Environmental/Water Utility Systems

course outline

Review of Learning Objectives
Module 1

- Introduction to Industrial Microbiology
- Definitions Commonly Used in Microbiology

Module 2

- Common Contaminants Based upon USP <60> and <62> and In-House Microorganisms
- Environmental Contamination and What it Means to You
- Cross Contamination within A Manufacturing Facility

Module 3

- Environmental Testing and Associated Challenges
- Management of Your Environmental/Water Utility Systems

Question and Answer Session
Assessment Opportunity

course instructor

Barry A. Friedman, Ph.D., is a Senior Consultant in the Biotechnology, Regulatory Compliance, Microbiology and Aseptic Processing arena. From 2000 to 2007, Dr. Friedman was associated with Cambrex Bio Science Baltimore, a contract manufacturer of GMP bulk biopharmaceuticals located in Baltimore, MD. In that capacity as the Director, Quality Control, he managed a multi-shift Department of thirty-one individuals involved in Client management, the receipt and testing of raw materials, environmental monitoring and microbiology, analytical chemistry, and QC compliance for the production of Phase 1, 2, 3 and commercial products manufactured from bacteria, yeast, and mammalian cells. In this capacity, Dr. Friedman enjoyed many clients and regulatory compliance interactions.

Dr. Friedman has over 30 years of industrial managerial experience in various aspects of biopharmaceuticals and medical devices to include regulatory compliance, expert witness assistance, quality control, sterility assurance, microbiological/analytical validations, and fermentation technology. In addition to the associations listed above, other associations have included Chesapeake Biological Laboratories, W.R. Grace, Sigma Chemical Co., Sherwood Medical, Becton Dickinson, American Cyanamid, and Union Carbide.

Dr. Friedman is a frequent seminar and webinar speaker and specializes in the areas of regulatory compliance, internal auditing, aseptic processing for sterile drug products, USP and Warning Letter "dissection", multi-departmental interactions, validations and the requirements for the manufacture of Phase 1, 2 and 3 clinical trial materials. He has recently given presentations for the FDA, PDA, PTi, TungstenShield, IPA (Canada), Executive Conference Corp., and Pharmig (UK). He is a member of ASM and PDA. He served as a Captain in the Medical Service Corps, U.S. Army, and is the past President and Treasurer of the Capital Area Chapter, PDA. He recently received the James Agalloco award from PDA which is awarded to a PDA faculty member who exemplifies outstanding performance in education.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org