COBBLESTONE

COURSE ID 3090

NEW!

Management of Pharmaceutical Water in a GMP Environment

DIRECTED BY

Barry Friedman Ph.D. — Senior Consultant

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Pharmaceutical Water Systems
- Assay Requirements & Testing
- Water System Design
- Water Sampling and Requirements
- Warning Letters
- Troubleshooting the Water System

about the course

Knowledge of the microbiology of water in a GMP environment is critical to the health of any water system being used to produce a pharmaceutical or biotechnology product. Even companies manufacturing tablets need to be aware of the quality of the water that may be contacting their process or product. The well-being of a facility revolves around the health of each water system within that facility. How often have we learned of a facility being closed for weeks at a time because of a water system that has exceeded its microbiological specifications?

This 90-minute accredited and interactive training will examine a variety of the issues surrounding water in a facility to include the testing of each unit water operation and to what extent. It will cover testing requirements during commissioning and testing on an ongoing basis. The webinar will examine Quality Risk Management (ICH Q9) and discuss how a properly developed Facility Water Validation Plan may lead to a logical, reduced requirement for testing over time.

The training will also explore the time requirement for testing before reduced testing might occur and why some organizations refuse to accept this pathway.

The objective of this webinar is to assist those involved in the development of a process or the manufacturing of a product to explore water, as a raw material (component) in a GMP environment, the requirements for potable water, purified water (PW), water for injection (WFI) and clean steam to assure that they are meeting the current USP, EP, JP and FDA requirements.

Attending the training with your Project Team will be most beneficial to the group.

who should attend

This 90-minute 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
- Manufacturing
- Quality Assurance
- R & D
- Project Management
- Regulatory Compliance
- Quality Control
- Validation

learning objectives

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

- Outline how to develop a water sampling system and its test frequency.
- Define the "Health" of a water system based upon test results.
- Explain the differences between USP, EP and JP water requirements.
- Identify the use of Alert and Action Levels vs. Specifications and what is meant by each.
- Choose when microorganisms should be identified and the preferred methods.
- Show the requirements for in-house vs. purchased water.
- Examine the determination of various validations that supplement the maintenance of a USP Purified Water or Water for Injection system.
- Determine how to diagnose and control a water system problem.

course outline

Review of Learning Objectives

Module 1: Exploration of Pharmaceutical Water Systems and how they are Assayed

- Pharmaceutical Water Systems
- Assay Requirements and Testing

Module 2: Design of Water Systems and Typical Critical Attribute Performance

- Design of Water Systems
- System Design and Typical Critical Attribute Performance

Module 3: Frequency of Water Sampling, Warning Letters, and System Troubleshooting

- Frequency of Water Sampling, Locations, and Test Requirements
- Warning Letters
- Troubleshooting the Water System

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 speaker who 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), and Executive Conference Corp. 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