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2-day In-person Seminar:

# Essentials Of USP Microbiology - Reading Between the Lines of the USP General and Information Microbiology Chapters

By: **Barry A. Friedman, Ph.D,** Consultant in Biotechnology, Regulatory Compliance and Aseptic Processing Arena

**Location :** Chicago, IL | June 25-26, 2020




## SPEAKER

**Barry A. Friedman, Ph.D,** Consultant in Biotechnology, Regulatory Compliance and Aseptic Processing Arena

Barry A. Friedman, PhD, is a Consultant in the Biotechnology, Regulatory Compliance and Aseptic Processing Arena. Dr. Friedman possesses over 30 years of industrial managerial experience in various aspects of biopharmaceuticals and medical devices to include regulatory compliance, expert witness testimony, GLP/GMP, quality control, auditing, sterility assurance, microbiological/analytical validations and fermentation technology.

Prior to becoming an independent consultant, Dr. Friedman was associated with Cambrex Bio Sciences, a contract manufacturer of GMP bulk biopharmaceuticals located in Baltimore, Maryland. As the Director of 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 client and regulatory interactions, both domestic and international.

Prior to 2000, Dr. Friedman was the Laboratory Director for Chesapeake Biological Laboratories, a contract Aseptic Fill n' Finish manufacturer located in Baltimore, Maryland. In addition to the professional history listed above, other associations have included W.R. Grace, Sigma Chemical Co., Sherwood Medical, Becton Dickinson, American Cyanamid and Union Carbide.

Dr. Friedman received his B.S. degree in Microbiology from Ohio State University, his M.S. from Michigan State University in Microbial Genetics, and his PhD from Ohio State University in Microbiology.

## LEARNING OBJECTIVES

- Understanding the various General and General Information USP Chapters that apply to microbiology
- The focus of the chapters to include those that primarily involve non-sterile and sterile applications
- Chapters that involve the environment
- Examining the changes within the various Chapters that have recently occurred and how to interpret them
- Review areas that are often overlooked
- Study issues that continue to exist between the USP, EP and JP
- Examine the new regulatory attitude that is occurring with non-sterile products
- What now constitutes a "specified" and “objectionable” microorganism
- Explore Form FDA 483s and Warning Letters for microbiological applications

# COURSE DESCRIPTION

The objective of this two day "Essentials of USP Microbiology" seminar is to explore USP General and General Information Chapters to learn which are available and to confirm that those that you are using are being used correctly. USP documents that will be reviewed include:

- USP <51> Antimicrobial Effectiveness Testing,
- USP <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests,
- USP <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms,
- USP <71>Sterility Tests,
- USP <1072> Disinfectants and Antiseptics,
- USP <1111> Microbiological Examination of Nonsterile Products,
- USP <1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products,
- USP <1113> Microbial Characterization, Identification, and Strain Typing,
- USP <1116> Microbiological Control and Monitoring of Aseptic Processing Environments

Various team exercises will be conducted to allow the participants to use these USP documents to solve "real life" problems. Plan to bring a cross-functional group of your personnel to attend this invaluable two day seminar.

# AGENDA

## Day 1 (8:30 AM – 4:30 PM)

**Registration Process: 8:30 AM – 9:00 AM**

**Session Start Time: 9:00 AM**

- Overview of the General and General Information USP Chapters that apply to microbiology
- Focus upon those Chapters that primarily involves both non-sterile and sterile applications
- Learn how Chapters that involve the environment impact all other USP Chapters
- Defining the differences between a “Controlled” and “Classified” environment and how they impact the USP Chapters
- Review recently changed USP Chapters and how to interpret them
- Team exercises to include commonalities between the various USP documents

## Day 2 (8:30 AM – 4:30 PM)

- Review of areas of USP microbiology that are often overlooked
- Study issues that continue to exist between the USP, EP, and JP
- Examination of the new regulatory attitude that is occurring with non-sterile products
- What now constitutes a “specified” microorganism
- Team exercises
- Case Studies and recent Warning Letters

# WHO WILL BENEFIT

- Manufacturing
- Product Development
- Project Management
- Quality Assurance
- Quality Control
- Regulatory Affairs
- Regulatory Compliance

# TOPIC BACKGROUND

Microbiology plays a role throughout the manufacture of pharmaceutical products. Whether the final product is non-sterile or sterile, the bioburden exists from the raw materials, throughout the process and/or within the product's environment (water and HVAC) to the final product. A critical review of the overall microbiological process will determine whether the critical "in-process" points permit the final product to meet its acceptance criteria. In addition, any "objectionable" or "specified" microorganisms that may be encountered during the procurement of raw materials and the processing must be considered.

Whether you are testing a starting material (component), an in-process sample, the Active Pharmaceutical Ingredient (API), final product (whether non-sterile or sterile), the environment to include controlled and classified areas or the HVAC, you should be aware of the critical role the microorganisms play throughout. You should be aware of the various microbiological related documents, e.g., raw material sampling criteria, in-process, API, final product, environmental and utilities, (many of which have USP microbiological documents as the "bedrock" for building these documents, to determine whether the SOPs, validations as well as government and other regulatory body document requirements are being maintained to assure the control required to permit the final product to enter the marketplace as safe.

# Registration Form

## Registration Information:

- **Register Online.** Click Here Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-201 871 0474.
- Call 201 871 0474 or Fax your PO: 253 663 7224 Pay your check to "PMA Conference Management" and Mail the check to: PMA PO Box 2303, Falls Church VA 22042. Please fill this form with attendee details and payment details and fax it to 253 663 7224

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**Seminar Topic:** Essentials Of USP Microbiology - Reading Between the Lines of the USP General and Information Microbiology Chapters

Date & Location: Chicago, IL | June 25-26, 2020.....

Attendee Details: Registration fee $1899

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|---|---|---|---|
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| Attendee 2 | | | |
| Attendee 3 | | | |
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