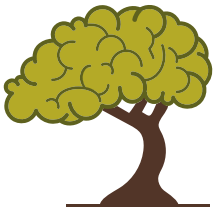
ABOUT THE INSTRUCTOR

Paula Peacos, M.S. has over 25 years of industry experience as a Microbiologist. She began her career as an entry-level bench analyst and has held various management-level positions of increasing responsibility over the years, including Lab Supervisor/Manager, Department Head, Global Site Representative and Corporate Microbiologist. Ms. Peacos has worked for contract manufacturing organizations as well as small, mid-size and large pharmaceutical organizations. She has extensive experience in clinical and commercial production of aseptically processed products, biological API/drug substances, cell therapies and nonsterile products in addition to microbiological laboratory management.

Ms. Peacos has also performed and/or supported compliance audits internationally as a microbiological SME. Ms. Peacos is an experienced trainer and mentor. She has developed and implemented customized developmental and remedial training programs on topics ranging from aseptic technique and proper clean room behaviors to deviation investigations and change control.

In recent years, Ms. Peacos has published several articles and delivered presentations at major industry meetings on topics such as risk assessment and using contamination rates for trending analysis outside of the aseptic environment. She is currently employed as a Senior Consultant with ValSource, Inc.



For more information, or to schedule a training session at your facility, please contact:

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PRINCIPLES OF EFFECTIVE CONTAMINATION CONTROL FOR THE NON-MICROBIOLOGIST

This full-day course is specifically designed to meet the unique needs of personnel who perform a job function in the production environment with little or no formal microbiological background or training. This course explains in practical terms the strengths and weaknesses of existing contamination control and detection methods and demonstrate how each job function plays a critical role in the success or failure of a facility's contamination control program.

VALSOURCE

A better solution. Delivered.

WHY YOU SHOULD ATTEND

Everyone who enters the production environment at any time and for any purpose has a critical role in ensuring efficacy of the facility contamination control program. The most seemingly insignificant aspects of one's daily job function can have a major impact on the success or failure of the program. For individuals who have little or no formal microbiological background or training, it can be difficult to recognize these impacts and to identify contamination risks in the production environment. This training session is intended to provide the non-microbiologist with the knowledge and tools necessary to effectively own and fulfill their role in ensuring the success and sustainability of their facility's contamination control program.

The information contained in this interactive session is presented in a frank and practical manner that the non-microbiologist can easily incorporate and apply. Common myths and misconceptions concerning existing contamination control and detection methods are addressed, and their strengths and weaknesses identified. The potential consequences resulting from poor contamination control will also be discussed. Attendees will gain holistic and practical knowledge of the principles of contamination control by exclusion and how to apply them to their daily activities, improving overall performance and efficacy and driving continuous improvement.

LEARNING OBJECTIVES

After completing this course, attendees will be able to:

- Explain how microorganisms enter and move through a facility, and identify the risks they pose to both process and product.
- Explain the philosophy of contamination control by exclusion and its significance.
- Identify the strengths and limitations of their own facility's contamination control program, and apply principles learned to their daily activities to help mitigate the limitations.
- Identify potential contamination risks in the production environment.
- Explain the criticality of their individual role in the success or failure of the contamination control program.
- Demonstrate improved overall job performance and efficacy.
- Demonstrate individual ownership in the contamination program, and drive continuous improvement and sustainability.

WHO SHOULD ATTEND

This course is designed for anyone who performs a job function in the production environment who would like to broaden their base of knowledge in microbiology. This includes individuals responsible for process development, clinical and commercial manufacture of pharmaceutical and biological dosage forms, sampling and testing, as well as ensuring the high quality of those products and the facilities they are produced in. Other related industries benefit as well.

Individuals in the following or related roles will benefit from this course:

- Senior quality managers
- Quality professionals
- Compliance professionals
- Production supervisors
- Manufacturing engineers
- Production engineers
- Process owners
- Quality engineers
- Quality auditors
- Development professionals
- Senior development managers
- Risk management
- Quality assurance/control
- Project engineers and managers, commissioning, validation, engineering and service providers
- Manufacturing operations and facilities professionals