Investigation of Microbial Contamination in Sterile and Non-Sterile Products

Location: Your Computer  Offering #: 1207-706  Priority Code: 520

This is a 2-part series. For maximum training benefit, participants are encouraged to attend Control of Microbial Contamination in Manufacture of Sterile and Non-Sterile Products. However, each session may also be taken individually. Maximize learning and minimize expense: Register for both parts and save $100 OR take either as a stand-alone course.

WHO SHOULD ATTEND

This course is intended for persons who are directly involved with the manufacture of sterile drugs and medical devices, as well as other products that are required to be free of certain objectionable organisms. It is recommended for:

• Production Managers
• Environmental Monitoring Personnel
• Process Design/Engineering Personnel
• QC/QA Managers
• QC/QA Lab Personnel
• Maintenance Managers

LEARNING OBJECTIVES

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

• Define the steps to follow in the event of microbial contamination in product
• Analyze product contamination utilizing essential clues such as the identification of microbial contaminants and their historic occurrence at the manufacturing facility
• Describe and discuss problematic organisms and how improper equipment/process design, improper maintenance, inadequate procedures, lack of training and other factors can contribute to microbial contamination

COURSE DESCRIPTION

This 90-minute accredited online course provides an overview of the investigation of microbial contamination in manufacturing processes and products. Product contamination can cause infection in the end user and can result in financial loss to the manufacturer. Detection of microbial contamination requires prompt attention. A positive test for microbial contamination in product will be discussed and the analogy made to a criminal investigation. The formation of a cross-functional team is essential to the investigation process. Investigation basics will be presented along with specific known problematic organisms. Examples of design flaws, inadequate maintenance, lab induces failures and other problems that can lead to product contamination will be provided.

Review of Learning Objectives

Module 1:
• Definition of microbial contamination and its potential root causes
• The importance of microbial identifications to the investigation process
• Investigation basics

Module 2:
• Identifications of microbial contaminants as clues to the source
• The laboratory as a source of microbial contamination
• Microorganisms with known resistance to sterilization processes

Module 3:
• Water as a source of microbial contamination
• Design flaws and system failure examples leading to microbial contamination of product
• The laboratory as a source of false positive tests

Question and Answer Session

For more information see reverse side

CfPA
The Center for Professional Advancement
Accredited Technical Training Worldwide

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Daniel J. Spangler, M.S. Consultant, Microbial Contamination Solutions

Daniel Spangler has over 20 years experience in Microbiology/QC laboratory management roles in the manufacture of sterile OTC, prescription, and parenteral drugs (Coopervision, IOLAB, OJU Pharmaceuticals, Enzon Pharmaceuticals, and Bristol Myers-Squibb) and sterile medical devices (Ethicon, Inc.). He also has 3 years experience as Principal Scientist in medical device R&D (Ethicon, Inc. and Arrow International, Inc., and Teleflex Medical). In his microbiology management role, Dan has gained hands on knowledge and expertise regarding the sources of microbial contamination in manufacturing processes, and has developed insight into contamination prevention, process troubleshooting, and remediation. He has shared his experience and expertise in presentations at numerous corporate level and professional conferences (ASM, Puerto Rico Chapter) on control of microbial contamination in water systems and investigation of sterility test failures.

TUITION AND REGISTRATION

TUITION* – Single Rate: U.S.$295.00 per person  
Group Rate: U.S.$245.00 per person**

Attend both parts & SAVE $100!  
Tuition for entire series – Single Rate: U.S. $490.00  
Group Rate: U.S. $390.00


For Questions and Information call Customer Service at 732-613-4500.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

System Requirements: PC-based attendees: Windows(R) 7, Vista, XP or 2003 Server/Macintosh(R)-based attendees: Mac OS(R) X 10.4.11 (Tiger(R)) or newer

ACCREDITATIONS

The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500 McLean, VA 22102. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. The Center for Professional Advancement is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal training and a minimum score of 70% on the assessment. The Center for Professional Advancement is therefore authorized to offer IACET CEUs at a rate of .1 CEU per contact hour (rounded to the nearest tenth) for its programs that qualify under the ANSI/IACET Standards.

WHO WE ARE

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately three hundred and fifty short courses in 18 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. CfPA courses are offered in a variety of formats – Public offering, Client Site and Online – to fit you or your company’s training needs.

For more information visit our website at www.cfpa.com

COURSES OF INTEREST

- A Survey of Microbiology for the Pharmaceutical, Biotechnology, and Medical Device Industries–An Online Course 
  course ID# 2317
- Clean Room Technology Basics in a Nutshell (First in a Three Part Series)–An Online Course 
  course ID# 2420
- Control of Microbial Contamination in Manufacture of Sterile and Non-Sterile Productss–An Online Course 
  course ID# 2215
- Critical Process Cleaning and Cleaning Validation 
  course ID# 1867
- Lyophilization Technology 
  course ID# 279
- Microbiology Fundamentals Relating to Clean Rooms (Second in a Three Part Series) –An Online Course 
  course ID# 2426
- Operation of the Clean Room (Third in a Three Part Series) –An Online Course 
  course ID# 2427
- Sterile Products: Formulation, Manufacture and Quality Assurance 
  course ID# 435

ABOUT ON-DEMAND:

Our pre-recorded on-line training courses are available for viewing at your convenience at your computer. Register for a CfPA on-demand course, your registration will be processed within two (2) business days, after payment and registration are complete you will receive an email from onlinetraining@cfpa.com with your password to access the on-demand course. You will have two (2) business days to view the course. You MUST complete all polls and the course evaluation before you can receive your accreditation certificate for this course.

TERMS AND CONDITIONS

*Payment: Tuition payable in US funds net of all charges. Payment is due at time of registration in the form of a credit card. Please contact CfPA’s Customer Service for other payment options.

**Group Rate: The Group Rate is for two or more enrollments, up to five registering from the same company at the same time. For groups of six or more, please contact Customer Service for group pricing.

Cancellations/No Show: “Live” – Registrants may cancel up to two working days prior to the course start date and will receive a letter of credit to be used towards a future course up to one year from date of issuance. No credit will be issued for no-shows and/or cancellations less than two working days prior to the course. “On-Demand” – No refund or credit will be issued for no-shows and/or cancellations of on-demand training courses. CfPA is not responsible for any outside related costs incurred by registrant’s cancellation.