2 Days Seminar : Aseptic Processing and Validation in the Manufacture of Biotech and Pharmaceutical Products

Date : Mar 18, 2019 - 08:30 AM - Mar 19, 04:00 PM

Event URL : http://www.BostonEventsList.com/events/2-days-seminar-aseptic-processing-and-validation-in-the-manufacture-of-biotech-1549618197

Organizer : WCS

Venue : Hilton Garden Inn San Diego

Location : Hilton Garden Inn San Diego / Del Mar3939 Ocean Bluff AveSan Diego, CA 92130United States,
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Overview

This course will provide an overview of the requirements for aseptic and bulk manufacturing operations, including facility design, contamination controls and acceptable personnel behaviors.
Cleanroom classifications and the techniques for proper cleaning and disinfection are presented; along with a high-level overview of microbiology in regards to cleanroom environmental monitoring and the associated impact to product and patient health and safety. This course will also review the guidance provided in USP to ensure compliance with regulatory expectations are met.

Course Objectives

At the completion of this course, attendees will be able to:
• Explain the difference between Aseptic and Bulk processing
• Understand facility and personnel requirements necessary to maintain microbial control
• Explain basic principles of microbiology and microorganism recovery in relation to cleanroom environmental monitoring (EM) and impact to product
• Understand the gowning requirements associated with different cleanroom classifications

• Explain basic principles of aseptic processing, including:
o Cleanliness classifications
o Process differences between aseptically produced and terminally sterilized product

o Relation of manufacturing and handling procedures to sources of product contamination
o The differences between cleaning, disinfection and sanitization
o Proper cleaning / disinfectant technique
o Elements of a robust environmental program and why EM is important
o The role of isolator technology
• The purpose of media fills, and elements critical to their success
• Identify behaviors that are or are not appropriate when working in controlled areas, and why
• Identify ways that they can impact/improve site-specific EM and aseptic behavior issues

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Session Highlights

Topic 1: Basic Micro Review

• The role of environmental monitoring
• Types & sources of microorganisms
• The impact of microorganisms on product and patient health and safety

Topic 2: Review Aseptic Processing Basics

• Cleanliness classifications
• Process differences between aseptically produced and terminally sterilized product
• Relation of manufacturing and handling procedures to sources of product contamination
• The differences between and the purposes of cleaning, disinfection and sanitization
• Proper cleaning techniques
• The role of isolator technology

Topic 3: Review Clean Area Behaviors

• Personnel gowning requirements
• Good clean area behaviors/practices
• Practices to avoid – and why
• Review site-specific EM/aseptic behavior observations/risks & ask attendees to brainstorm ways to change/improve/eliminate these behaviors & risks

Topic 4: Aseptic Validation

• The purpose of media fills, and elements critical to their success

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Who will benefit

This is a two-day course for people who need to understand the technical fundamentals of

aseptic processing or who are responsible for aseptic operations in a lab, pilot or commercial setting. This aseptic training course is ideally suited to industrial microbiologists, scientists and engineers either with technical or managerial responsibilities

Operations employees who are required to enter controlled environments as part of their job function – includes some or all of the employees in the following departments:
o Production
o QC Micro
o Engineering & Validation
o Facilities / Maintenance

Event Categories :