CMO Supplier Quality Agreements

Date : Mar 21, 2019 - 01:00 PM - 02:00 PM

Event URL : http://www.BostonEventsList.com/events/cmo-supplier-quality-agreements-mar-2019

Organizer : WCS

Venue : online

Location : WCS Consulting Inc.3190 Stirling Rd, Unit K4 ,Hollywood, FL 33021,
Hollywood, Florida, US, ZIP: 33021
Phone: 844-267-7299 | 954-947-5671 Â

Overview

It is important that the sterile filtration process is fully understood and properly validated for your particular application. The process requirements and validation needs differ based on the filtration requirement. This webinar will offer attendees a comprehensive understanding of the same while emphasizing the different types of sterilizing filtration available and their application to your particular system. For instance, the application of sterile filtration to use-point compressed air will be discussed in detail.

Why Should You Attend

This course will offer a broad review of:

- Different filtration media with the construction characteristics and properties of each detailed
- A typical pharmaceutical sterile filtration system with its individual components
- Engineering schematics
- Microbiology and particle retention mechanisms
- Integrity testing methods and media qualification
- Procedures for the sterilization of the filter (SIP, autoclave, etc.)

The proper validation of sterile filtration is important to ensure that the filter will reproducibly remove undesirable components (bioburden) while allowing passage of desirable components (drug product). The operating parameters of time, pressure and temperature will be fully discussed along with the filter's potential effect on the product (compatibility, leachables, fibers, endotoxin, etc.). Microbial retention challenge testing is one of the validation requirements and the instructor will offer insights on the same.

At the end of the course, the instructor will present a compilation of all FDA/EU GMP regulatory guidances concerning sterile filtration. In keeping with these guidances and requirements, the responsibilities of the filter manufacturer vs. the filter user will be thoroughly analyzed.

Session Highlights

- Sterile Filtration - Importance of Quality
- Sterility Assurance of Sterile Filtration
- Sterile Filtration System Design
- Discussion of Different Filtration Media Properties and Retention Mechanisms
- Methods for Sterilization of Filters
- Validation of Sterile Filter Systems
- Microbial Retention Challenge Testing
- Integrity Testing
- Product Compatibility Testing
- Extractable/Leachable Testing
- Regulatory Requirements

Who Will Benefit

This webinar will provide valuable assistance to all personnel in:

- Quality Assurance
- Environmental Monitoring
- Microbiology

- Manufacturing
- Validation
- Engineering

Event Categories :