GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Webinar on

Sterile Filtration Of Pharmaceutical Products - What You Need To Know To Meet Validation And Regulatory Requirements

Date : 16 May 2019

Learning Objectives

- *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*

GRC EDUCATORS
Online Training Hub
Axons Technology and Solutions

This webinar will give you a comprehensive understanding of this important subject with an emphasis on the different types of sterilizing filtration available and their application to your particular system.

PRESENTED BY:

Roger Cowan is the founder and owner of R Cowan Consulting Services LLC, a consulting company specializing primarily in the area of pharmaceutical contract manufacturing. He has 37 years of experience in pharmaceutical quality assurance and manufacturing. In his career, Roger has held various manager/director positions in Quality Assurance, QC Laboratory, Technical Services Validation, Manufacturing, and Clinical Supply manufacturing and distribution.

GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

Date : 16 May 2019

Time : 01 : 00 PM EST

Duration : 60 Minutes

Price: $229

Webinar Description

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 give you a comprehensive understanding of this important subject with an emphasis on the different types of sterilizing filtration available and their application to your particular system. For example, the application of sterile filtration to use-point compressed air is discussed in detail.

A review of the different filtration media is provided with the construction characteristics and properties of each detailed. A detailed description of a typical pharmaceutical sterile filtration system with its individual components is provided. Engineering schematics are included. Microbiology and particle retention mechanisms are discussed.

Integrity testing methods are detailed as well as media qualification. Procedures for the sterilization of the filter are presented (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 are fully discussed as well as the filters potential effect on the product (compatibility, leachables, fibers, endotoxin, etc.). Microbial retention challenge testing is one of the validation requirements.

Finally, a compilation of all FDA/EU GMP regulatory guidance concerning sterile filtration is presented. Related to this; the responsibilities of the filter manufacturer vs. the filter used is fully discussed.

Who Should Attend ?

Quality Assurance

Environmental Monitoring

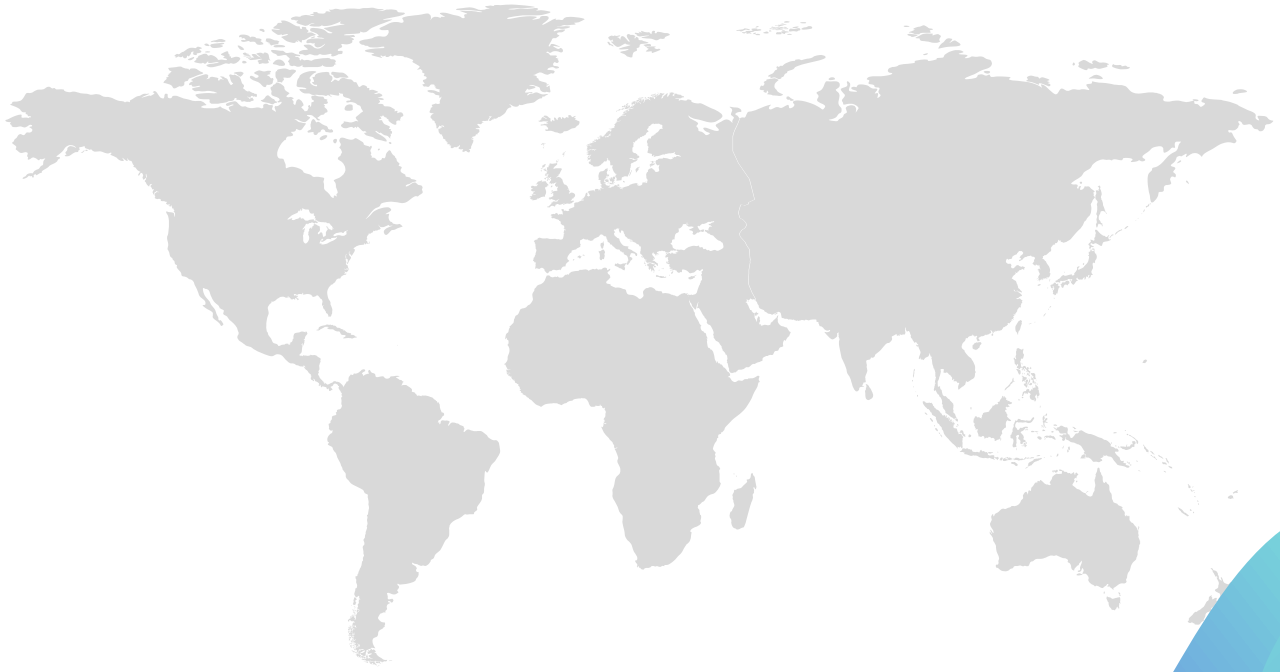
Microbiology

Manufacturing

Validation

Engineering

Maintenance



GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

To register please visit:

www.grceducators.com
support@grceducators.com
740 870 0321