

Sterilizing Grade and Prefilter Course

- Course Name: Sterilizing-Grade & Prefilter Course and Workshop
- Overview: The lecture will cover form and function of sterilizing and prefilters. Topics covered include; various mechanism of particle and microbial removal, pore size ratings, typical filtration applications and overview on functionality and integrity testing. This Course will review current standards and regulatory requirements regarding sterilizing & pre-filtration and discuss industry trends and developments. A theoretical and practical review of bacterial retentive filter Integrity Testing with Do and Don't and trouble shooting. A hands-on demonstration of Integrity Testing and filter through-put studies comprises the workshop sessions.
- Description: This Course presentation will examine the following key topics;
- Definition of sterilizing grade & prefilters and pore size ratings.
 - Terminology and definition of key terms and filtration functions
 - Filtration removal mechanism; sieving, adsorption, depth removal.
 - Mechanisms of entrapment / removal in liquids /gases.
 - Types of filter media; membrane verse depth filters
 - Material of construction: how to choose the right media
 - Functionality and Integrity Testing review.
 - Qualification and validation review.
 - Extractables and Leachables Studies, when and why?
 - Overview of current industry standards and regulatory requirements.
 - Review of Single-Use Disposable technology concepts.
- Objectives: Key concepts that will be reviewed:
- Be able to identify process applications for sterilizing & prefilter usage.
 - Understand the concepts of filtration mechanisms in liquid and gases.
 - Determine filtration media uses for various filtration applications.
 - To be able to specify and qualify filters for these applications.
 - Understand Integrity Testing and troubleshooting methods.
- Rational: Course will review the latest industry filtration technologies and standards with an overview of regulatory requirements. Why and how to determine which filter, the media and pore ratings are appropriate for various filtration applications. Course is designed for the experienced as well as those new to biopharmaceutical processes. The need to know current requirements for specifying sterilizing grade and prefilters in biopharm processes.
- Who Should Attend: Process Development Engineers and Scientists, Pilot-Plant Staff, Production management and operations, Validation & QA/QC & RA personal.

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DURATION: One Day with workshop session

Materials:

- A/V Equipment
- Basic Laboratory Chemicals & Glassware
- Filterability Through-put testing equipment with air pressure
- Sterilizing-grade filters (0.2um & 0.45um) + prefilters (47mm Discs)
- Personal Safety Equipment
- Integrity Testing Demonstration Kit
 - Pressure gauges
 - Syringe filters (0.1/ 0.2/ 0.45/ 0.8um + 0.2um (PTFE))
- Filter Integrity Test Instrument, e.g., Sartochek 4