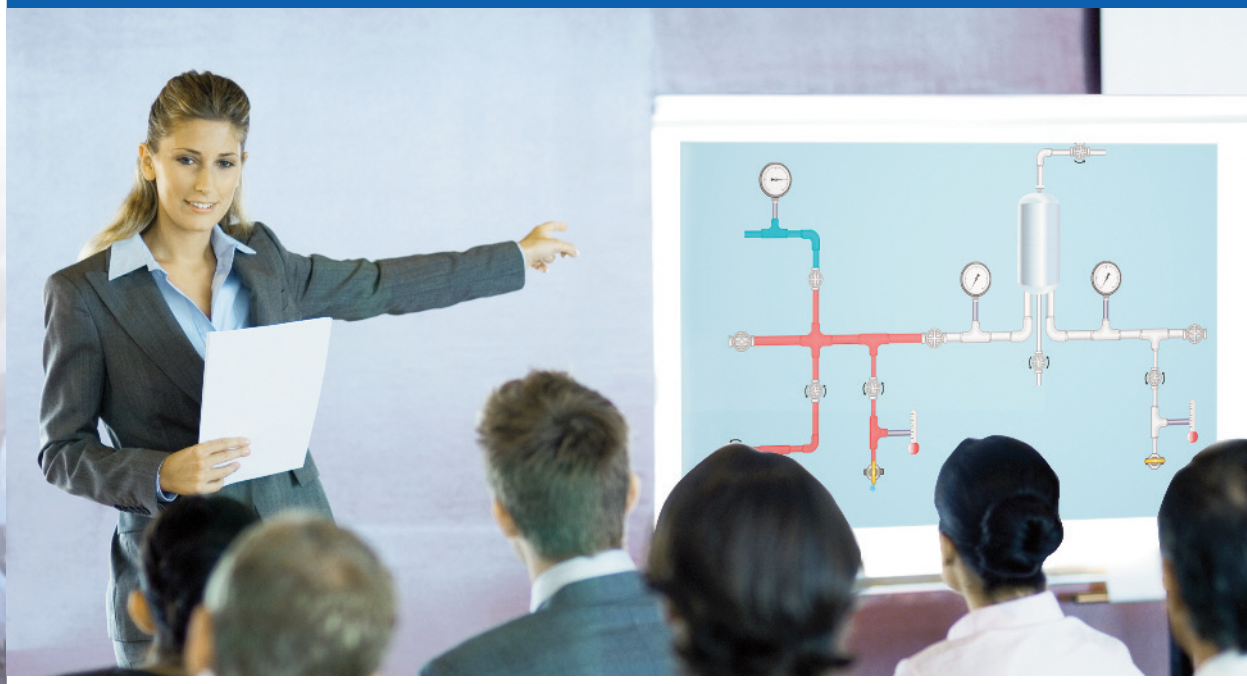
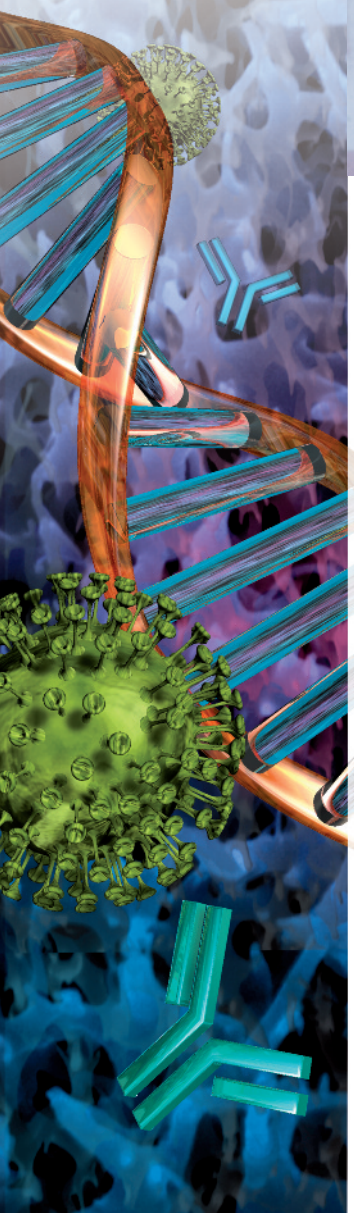
PALL Life Sciences

USD 2757

Filter Sterilization Training - Best Practices





One of the primary elements of a successful sterilizing filtration process is the sterilization of the filtration assembly[1], most commonly achieved using steam under pressure[2]. Examples of processes requiring sterilization of sterilizing-grade filters are cell culture media and fermentation air, sterile bulk filling, sterile tank vents, and sterilization of drug product prior to aseptically filling. If not conducted properly, the steaming of filters can result in filter damage due to excess temperature, high differential pressure, or degradation of the materials of construction[1].

In order to avoid these undesirable effects on the filter assembly from improper autoclave or *in situ* steam (Steam-in-Place or SIP) sterilization, operators requires a solid understanding of the conditions necessary to achieve sterility of the filter assembly or filtration system, while simultaneously preserving the integrity of the filter and other system components.

The goal of this training is to prepare operators to successfully steam sterilize a filter assembly without causing damage to the filter.

Course Description

The course is designed for manufacturing operators and relevant staff to secure an understanding of autoclaving and SIP, from terminology of steam sterilization (as discussed in PDA Technical Report No. 1)[2] to basics of good sanitary design. In addition to discussion of recommendations for successful autoclave and SIP processes such as those in PDA Technical Report No. 26, examples of step-through simulations of proper SIP processes of common system designs will be examined.

Features and Benefits

- Courses designed and led by experts in biopharmaceutical filtration applications
- Each course is customized to ensure maximum relevance to your operation following 1:1 discussion with our training experts
- Ensures optimal use of training budgets
- Can be held locally or at Pall's specialized training facilities
- Pall staff can work with your local training department to ensure course meets any specific requirements

Filtration. Separation. Solution.SM

Who Should Attend

- Manufacturing operators, supervisors, and managers requiring a working knowledge of moist heat sterilization techniques
- QC/QA staff
- Validation, process, and project engineers

Course Content

- Overview of Filter Sterilization
  - Methods and Key Aspects
  - Filter Construction
  - General Precautions
- Industry Guidance for Filter Sterilization
- Steam Basics
  - Steam and Steam Saturation
  - Why SIP?
  - Overview of Autoclave Sterilization
- Lethality and Fo Value
- Air and Condensate Removal
- Basics of Good Sanitary Design
- Autoclave Sterilization Recommendations
  - Simulations of Autoclave Processes
- Steam-In-Place Sterilization System
  - Simulations of SIP Processes
  - Demonstration using Live Steam (where applicable)
- Troubleshooting
  - Practical Workshops to Examine Typical Issues
- Discussion/Q&A

Course Objectives

The course delivery and content is customized to ensure that attendees:

- Can use steam to sterilize a filter
- Understand how to prevent damage to a filter or a system when sterilizing via SIP
- Understand good design principles for a system to be sterilized via SIP
- Understand the challenges of successful autoclave and SIP processes

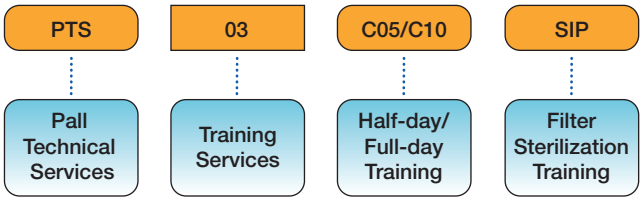
Additional Notes

- Course includes a discussion of the critical factors to consider in the steam sterilization process, a practical section to examine successful system design to be sterilized via SIP, as well as extensive troubleshooting sections to discuss issues encountered during SIP. Real-world scenarios are analyzed in workshops for troubleshooting and optimization.
- A Certificate of Training is included for all attendees who have successfully completed the course.

Course Duration

Training can be provided in a half day or full day depending upon your specific needs and depth of training required.

Ordering Information



Charges

Charges are based on customized course content.
Pall provides a fixed price in advance based on agreed course content prior to finalizing course agenda.

Contact Us

Contact your local Pall representative or email us to discuss your specific training requirements.

References

1. Parenteral Drug Association (PDA) Journal of Pharmaceutical Science and Technology - Technical Report No. 26 (Revised 2008): Sterilizing Filtration of Liquids; 2008 Supplement; Volume 62, No. S-5; Section 8.0: Sterilization Of Filters, page 40, paragraph 1

2. PDA Journal of Pharmaceutical Science & Technology - Technical Report No. 1 (Revised 2007): Validation of Moist Heat Sterilization Processes Cycle Design, Development, Qualification and Ongoing Control

PALL Life Sciences

Corporate Headquarters
Port Washington, NY, USA
+1 800 717 7255 toll free (USA)
+1 516 484 5400 phone
biopharm@pall.com e-mail

European Headquarters
Fribourg, Switzerland
+41 (0)26 350 53 00 phone
LifeSciences.EU@pall.com e-mail

Asia-Pacific Headquarters
Singapore
+65 6389 6500 phone
sgcustomerservice@pall.com e-mail

Filtration. Separation. Solution.SM

Visit us on the Web at www.pall.com/biopharm

E-mail us at biopharm@pall.com

International Offices
Pall Corporation has offices and plants throughout the world in locations such as: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Poland, Puerto Rico, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, the United Kingdom, the United States, and Venezuela. Distributors in all major industrial areas of the world. To locate the Pall office or distributor nearest you, visit **www.pall.com/contact**.

6/11, Xk, GN10.4145 USD 2757