ASEPTIC PROCESSING OF PHARMACEUTICAL AND BIOTECH PRODUCTS

2 DAYS, LIVE VIRTUAL TRAINING WITH AN INSTRUCTOR

Introduction

Managing sterility is not only a critical factor in pharmaceutical manufacturing but also the most difficult one. Aseptic processing is critical to patient safety and you are not unaware of this fact. As a result, FDA scrutinizes every manufacturing unit intensely to eliminate non-compliant setups.
To adhere to this demand and raise the benchmark of aseptic manufacturing, we have curated a 2-day long virtual course for esteemed professionals like you. Thus, if you are associated with any department of biological and pharmaceutical manufacturing, this course will upskill your knowledge about every step.
Keep reading to understand the deliverables of the aseptic manufacturing training.

Course Overview

To tackle these, World Compliance Seminar has curated a course to guide you about handling manufacturing facilities effectively. The core benefits of the aseptic processing course include:

- Managing the complexity of working with highly potent ingredients and executing fill-finish effectively
- Identifying and overcoming issues with single-use system
- Exploring the latest technologies available in aseptic filling
- Best practices to eliminate contamination risk through barrier technology
- Deeper insights from regulatory panels across the leading countries in the world
- Understanding the role of robotics in aseptic processing
- Examining strong trends in small-scale and ready-to-use products

This course equips you with the knowledge to evaluate the risks and failures in the unit. Moreover, you will be able to identify the repetitive penalties being imposed on the organization due to disappointing manufacturing practices. By the end of this seminar, your products will be ready to pass sterility tests and FDA audits without any hiccups.

Who Will Benefit

Aseptic sterile technique training will benefit plenty of individuals such as:

- **Manufacturing professionals**: Get the right knowledge of basic principles and develop skills to control procedure setting
- **Project Manager**: Understand critical factors required to maintain compliance
- **Quality Control Professionals**: Decrease the inspections failures, cautionary letters, and agreement rulings
- **Reformulation and Formulation Developer**: Determine how to develop media fill simulations and work on the worst-case scenarios
- **Process Chemistry Specialists**: Learn the best repetition techniques for decisive media fill sizes

NEW FDA REGULATORY COMPLIANCE FOR DRUG AND BIOTECH PRODUCT COURSE

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Training Agenda

Aseptic Processing – Introduction

- The Disinfected Quantity Form
- Conservation and control of serious surroundings
- Expansion of procedures for process, standardization, Preventive Maintenance, CAPA, etc.
- Exercise of workers to include gowning
- Certification and assessment of variations
- Adulteration Sources in Sterile Manufacturing
- Subdivision Content Controls
- Cross Pollution Hazards
- Cleaning Process and Agents for Sterile Production

Developing Media Fill Requirements in An Aseptic Environment

- Form FDA 483s
- Equipment set up
- Sterilization process
- Media fills
- Smoke studies and their emphasis in Aseptic Production (ISO Class 5 facilities)
- Endotoxin sources

Know Your Faculty

Dr. Barry A. Friedman holds 30+ years of experience in aseptic processing, and regulatory compliance. Testing raw materials, environmental controls, microbiological factors, QC compliance, and analytical chemistry are his core expertise. Additionally, he has also worked on phases 1, 2, and 3, and commercially certified products obtained from bacteria, yeast, and mammalian cells. Since Dr. Friedman specializes in aseptic processing, internal audit, and regulatory compliance, you can discuss validation criteria and techniques to pass the FDA inspection

Aseptic Processing Of Pharmaceutical and Biotech Products

REGISTRATION FORM

Name **Email**

Organization **Department** **Position**

Phone **Mobile**

Register Online At www.worldcomplianceseminars.com

or by calling our offi ce : 844-267-7299

Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.