

Aseptic Processing



The most comprehensive program in the preparation of sterile parenteral products!



Features:

- Comprehensive two-week training program
- Almost 50 hours of hands-on laboratory training
- Faculty comprised of leading industry, academic, and regulatory experts
- Class size is limited to maximize student – faculty interaction
- Perfect balance of laboratory and lecture training using modern equipment and instrumentation
- Two full media fill campaigns

PDA Education – Where Excellence Begins
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Two five-day sessions allow for an in-depth look into an expanse of specific topic areas. These two sessions are scheduled approximately three weeks apart, allowing for intense, comprehensive learning with minimal impact to your job/organization.

With almost 50 hours of hands-on laboratory training and group project work, in addition to extensive lecture sessions, this program is the most complete aseptic processing training offered.

KEY TOPICS:

Week 1

- Definition and scope of aseptic processing
- Facility design, HEPA certification, velocity, and airflow studies
- Aseptic process simulations (media fills)
- Gowning, personnel qualification, and proper aseptic technique
- Basic microbiology, environmental monitoring, and control systems
- Sanitization techniques
- Filtration and liquid filter integrity testing
- Lyophilization

Week 2

- Reading and evaluating media fills
- Good documentation practices
- Rapid microbial identifications, sterility testing, and final product testing
- Sterilization
- New aseptic technologies
- Container/Closure testing

WHO SHOULD ATTEND:

Manufacturing: Director, Manager, Leader, Supervisor, Technician, Specialist

QA/QC: Director, Manager, Leader, Supervisor, Technician, Specialist

Validation/Engineering: Director, Manager, Leader, Supervisor, Technician, Specialist

Other Departments that would Benefit from this Program: Compliance, Regulatory Affairs, Microbiology, Training

BENEFITS OF ATTENDING:

- Learn to relate and incorporate each component of aseptic processing into one seamless operation for an overall improved process and finished product
- Understand the theory and practice behind personnel gowning qualification and aseptic technique to minimize risk of product contamination by personnel
- Use proper environmental monitoring techniques combined with a robust cleaning and disinfection program to avoid common sources of contamination in your facility
- Learn to incorporate good documentation practices into your aseptic processing program to facilitate regulatory compliance

LEARNING OBJECTIVES:

Upon completion of this program, you will be able to:

- Demonstrate an increased proficiency in techniques and skills relating to aseptic processing
- Evaluate and improve current aseptic processing procedures at your facility
- Limit risk for manual product contamination with airflow visualization studies
- Evaluate your environmental monitoring program to collect appropriate data and identify and interpret trends
- Incorporate proper gowning principles into a complete personnel qualification program
- Describe the importance of filter integrity testing when filtering water, gases, or proteinaceous solutions
- Develop robust media fill protocols, including appropriate interventions, observation, and documentation procedures
- Discuss finished product testing requirements
- Correlate basic microbiology concepts and techniques to multiple aspects of aseptic processing
- Integrate industry-approved sanitization techniques and disinfectant evaluation into a comprehensive contamination control program
- Interpret regulatory requirements for manufacturing sterile products produced by aseptic processing

FOR MORE INFORMATION:

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TWO WAYS TO REGISTER!*

Web: pda.org/2018aseptic | **Fax:** +1 (301) 986-1093

To read our Cancellation/Refunds/Substitutions policy, please visit pda.org/Courses/FAQ

*Registration is limited to allow active involvement and meaningful interaction with other attendees and faculty.

Attendees at PDA's U.S. manufacturing training facility.

To register before this course sells out, please visit pda.org/2018aseptic