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

pda.org/2018aseptic
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

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
- Sanitation 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

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.