Outline

Aseptic Process Simulation (APS) studies commonly referred to as Media Fills are a tool used in the qualification of aseptic manufacturing facilities of sterile pharmaceutical and medical device products.

The APS allows companies to assess the capabilities of their aseptic process from the sterilization of components to the final closure of the product containers in producing sterile products.

The use of quality risk management tools during the APS program design is key for its success. This course will discuss the fundamentals of designing and performing successful aseptic process simulation studies and will improve your knowledge on the following elements:

- The utilization of quality risk management tools for the APS program design.
- Use of risk tools for the selection of interventions to be challenged during APS studies.
- Evaluation of personnel proficiency and use of operating practices, personnel monitoring, qualification, requalification and loss of qualification status.

In addition, this course will discuss APS interpretation of results including incubation time and temperature, examination of units, qualifications for examining units, growth promotion of media, acceptance criteria and investigations.

Who should attend?

This course is intended for professionals associated with the management of aseptic manufacturing operations and pertaining to the Process Development, Quality Assurance, Quality Control, Regulatory Affairs, Sterility Assurance, Technical Services, Operations and Validation areas.

Vendors to the healthcare product manufacturing industry, contractors and anybody who needs a more thorough understanding on how to establish a risk based APS program will also greatly benefit from this course.

About the Instructor

Marsha Stabler Hardiman has over 20 years of experience as a Microbiologist working in the Pharmaceutical, Biotechnology and Medical Device fields. Marsha has a Bachelor in Biology from Western New England University in Springfield, MA. She has extensive experience in aseptic processing including process simulations for aseptically filled products. Over her career, Ms. Stabler has also established numerous EM programs for many different medical device, pharmaceutical and biotechnologies companies and has extensive knowledge in quality systems.

She currently serves the Parenteral Drug Association (PDA) Science Advisory Board, leads a PDA Task Force on Microbial Data Deviations and serves on the PDA Microbiology Meeting Planning Committee. She also serves as a Microbiology Expert - Notified Body regulatory inspector for CE certification of medical devices. She is on faculty at PDA’s Training and Development Institute and is a consultant to different companies on the implementation of quality risk management into their quality systems and validation programs. She provides many training courses on aseptic processing related topics and currently helps companies in reassessing their existing EM programs to re-select sample locations based on risk.

Learning Objectives

At the completion of this course, attendees will be able to improve their knowledge of current regulatory requirements for aseptic process simulations. They will also learn the importance of using quality risk management into APS design, microbiological testing, acceptance criteria and results interpretation.
# Course Schedule

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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>9:00am - 9:10am</td>
<td>Welcome and Introductory Remarks</td>
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<tr>
<td>9:10am - 10:40am</td>
<td>Fundamentals and Critical Aspects of APS</td>
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<td>10:40am - 11:00am</td>
<td>Break</td>
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<tr>
<td>11:00am - 12:30pm</td>
<td>Study Design, Equipment and Facility Considerations</td>
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<td>12:30pm - 1:30pm</td>
<td>Lunch</td>
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<tr>
<td>1:30pm - 3:00pm</td>
<td>Qualification of Personnel and Microbial Monitoring</td>
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<td>3:00pm - 3:20pm</td>
<td>Break</td>
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<tr>
<td>3:20pm - 4:00pm</td>
<td>Interventions and Use of Risk in APS</td>
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<tr>
<td>4:00pm - 4:45pm</td>
<td>Interpretation of APS Results</td>
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<td>4:45pm - 5:00pm</td>
<td>Questions and Answers</td>
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**REGISTER NOW!**

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Phone: (787) 704.6864
(787) 226.6803
(787) 399.3990

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1. Please type or print your name, address and affiliation.

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Business Address

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2. Course & Fees: REGISTER TODAY and take advantage of the group discount by having your entire team attend: SEND YOUR WHOLE TEAM! Send three or more individuals from the same company and receive 15% off in all registration (Registrations must be received together).

**Fees when you get registered in Process Simulations (Media Fills) for Aseptically Filled Products course:**

- [ ] Early Registration Fee: $795 (Due Date: August 14, 2014)
- [ ] Regular Registration Fee: $895

**Fees when you get registered in both courses (Process Simulations (Media Fills) for Aseptically Filled Products and Risk Based Approach for Environmental Monitoring):**

- [ ] Early Registration Fee: $1395 (Due Date: August 14, 2014)
- [ ] Regular Registration Fee: $1495

3. Please check the appropriate box

Check Enclosed ☐ Charge to: Master Card ☐ Visa ☐ AMEX ☐

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4. Return complete form with payment (Payment must be included to be considered registered) made to:

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Professional education interest: (Check all that apply):

- [ ] Validation
- [ ] Sterilization
- [ ] Parenterals
- [ ] Engineering
- [ ] Statistics
- [ ] Maintenance
- [ ] Microbiology
- [ ] Utilities
- [ ] Aseptic Processing
- [ ] Cleaning Validation
- [ ] Computer Validation
- [ ] Biotechnology
- [ ] HVAC
- [ ] Env. Monitoring
- [ ] Laboratory

**Confirmation:** Written confirmation will be sent to you once payment is received.

**Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made any time. If you are pre registering as a substitute attendee, indicate in the registration form. Should you be unable to attend, please inform us in writing prior to 10 days and a credit voucher will be awarded which is applicable to a training course one year from date of issue. Event Cancellation: ECHO reserves the right to modify the material or instructor without notice or to cancel the event. If the event must be cancelled, registrant will be notified as soon as possible and will receive a full refund of fees paid. ECHO cannot be responsible for airfare penalties or other cost incurred due to a cancellation. Course enrollment is limited for the benefits of all attendees; this necessitates early registration.