WORKSHOP: Hands-on Aseptic Technique and Sterile Compounding

Robin H. Bogner

- Professor, UConn
- B.S. Pharmacy (Rutgers U)
- M.S. (U Iowa), Ph.D. (Rutgers U) – pharmaceutics
- Teach (30 yrs.) pharmaceutics lectures and labs (including sterile compounding and an advanced compounding elective)
- Served on USP Compounding Expert Committee (2005-2010)
- FDA Pharmacy Compounding Advisory Committee (2017-
- Research focus is lyophilization, solubility, and reconstitution of lyophilized products.
Robin Bogner’s Disclosure Statement

The University of Connecticut has received a grant from Medisca Pharmaceutique based on a proposal authored by Robin Bogner to study drug stability in compounded oral liquids. There is no anticipated conflict or bias due to these activities.

Laura Nolan

- 35 years pharmacy experience
  - Hospital Pharmacy
  - Pediatric Pharmacy
  - Long Term Care pharmacy
  - Home care pharmacy
  - Epic trainer
  - Medical device trainer
- Sterile and non-sterile compounding instructor at UConn
Disclosure

• Laura Nolan has no actual or potential conflict of interest associated with this presentation.

<table>
<thead>
<tr>
<th>Time</th>
<th>Schedule for the day</th>
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<tbody>
<tr>
<td>8:30-9:30</td>
<td>Best Practices in Cleanroom Design and Facilities</td>
</tr>
<tr>
<td>9:30-10:15</td>
<td>Keeping your Cleanroom “Clean”</td>
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<tr>
<td>10:15-10:30</td>
<td>Break</td>
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<tr>
<td>10:30 – 11:00</td>
<td>Handwashing &amp; Garbing Practice updated in new &lt;797&gt;</td>
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<tr>
<td>11:00-11:45</td>
<td>Essentials of Aseptic Technique</td>
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<td>11:45-12:45</td>
<td>Lunch</td>
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<tr>
<td>12:45-1:15</td>
<td>Current and Proposed Requirements for Environmental Monitoring</td>
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<tr>
<td>1:15-1:45</td>
<td>SOPs for Environmental Monitoring</td>
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<tr>
<td>1:45-2:45</td>
<td>Cleanroom Design Activity</td>
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<td>2:45-3:00</td>
<td>Break</td>
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<tr>
<td>3:00-4:00</td>
<td>Handwashing, Garbing &amp; Best Practices in Aseptic Technique</td>
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<tr>
<td>4:00-4:30</td>
<td>Training Best Practices</td>
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<td>4:30-5:00</td>
<td>What’s Wrong with this Picture?</td>
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</tbody>
</table>

60% “lecture” / 40% active learning activities
Learning Objectives-Pharmacists

• Diagram a floor plan of a cleanroom complex.
• Calculate the air changes per hour (ACPH).
• Describe an environmental monitoring plan for a cleanroom complex.
• List elements of a standard operating procedure
• Demonstrate handwashing, garbing and aseptic technique
• Compare facilities and identify equipment for a cleanroom complex
• Identify errors or gaps in procedures and in facilities.
• Compare changes in USP 797

Learning Objectives-Pharmacy Technicians

• Diagram a floor plan of a cleanroom complex.
• Calculate the air changes per hour (ACPH).
• Compare facilities and identify equipment for a cleanroom complex.
• Demonstrate handwashing, garbing and aseptic technique.
• Describe an environmental monitoring plan for a cleanroom complex.
• List elements of a Standard Operating Procedure.
• Identify errors or gaps in procedures and in facilities.
• Compare changes in USP797
In preparation for documenting aseptic training

- Please turn your cell phones off
- Save your battery
- Charge it up at lunch if needed
- Be sure there is sufficient memory for a 10 min video