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.) pharmaceutical 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.

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

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’s Disclosure Statement

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

Disclosure

- 60% “lecture” / 40% active learning activities

Time | Schedule for the day
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8:30-9:30 | Best Practices in Classroom Design and Facilities
9:30-10:15 | Keeping your Classroom “Clean”
10:15-10:30 | Break
10:30-11:00 | Handwashing & Garbing Practice Updated in New 797
11:00-11:45 | Essentials of Aseptic Technique
11:45-12:15 | Lunch
12:15-1:15 | Current and Proposed Requirements for Environmental Monitoring
1:15-2:45 | SOPs for Environmental Monitoring
2:45-3:00 | Break
3:00-4:00 | Handwashing, Garbing & Best Practices in Aseptic Technique
4:00-4:30 | Training Best Practices
4:30-5:00 | What’s Wrong with this Picture?
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.
- Describe an environmental monitoring plan for a cleanroom complex.
- Demonstrate handwashing, garbing and aseptic technique.
- 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.