

# Compounding in the PharmD Curriculum

## Implications of USP 795, 797, and 800

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# Overview

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- UIC College of Pharmacy Compounding Curriculum
  - Lectures
  - Sterile labs
  - Non-sterile labs
- UIC College of Pharmacy Lab Setup
  - Sterile
  - Non-sterile
- USP 795, 797, and 800
- Limitations

# UIC COP Curriculum

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- Lectures

|                                   |                           |
|-----------------------------------|---------------------------|
| Dosage forms – theory and product | FDA                       |
| 795/797/800                       | Joint Commission          |
| Sterile compounding               | 503A/503B                 |
| Calculations                      | Hospital IV room pharmacy |

- Sterile compounding labs

|                              |                                  |
|------------------------------|----------------------------------|
| Ampules/vials                | Total parenteral nutrition (TPN) |
| Hazardous drugs              | Vancomycin batching              |
| Heparin dilutions            | Medication shortages             |
| Vancomycin/heparin line lock | Alteplase preparation            |
| Methylprednisolone eye drops | Methacholine asthma challenge    |
| LET topical solution         |                                  |

- Non-sterile compounding labs

|             |                          |
|-------------|--------------------------|
| Solutions   | Lotions                  |
| Suspensions | Suppositories            |
| Emulsions   | Troches                  |
| Ointments   | Capsules/divided powders |

# UIC COP Curriculum

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- First year – students act as technicians
- Second year – students act a pharmacists
  - Sterile and non-sterile practical at the end of the second year
- Teach “best practices”
- Teach what we can’t demonstrate

# UIC COP Lab – Old Setup

- Combined sterile and non-sterile space



# UIC COP Lab – New Setup

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- 2 “modes”: non-sterile vs sterile
  - Non-sterile
    - 3 rooms with 42 tables total



# USP 795

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- Garbing
- Clean work surface and balances before and after compounding
- Clean supplies after compounding
- Compounding record (abbreviated)
  - Name, strength, dosage form
  - Manufacturer/lot numbers/expiration dates
  - Date/time of compounding
  - Weights/measurements
  - Calculations
- BUD's
- Containment ventilated enclosure (CVE)/powder hoods



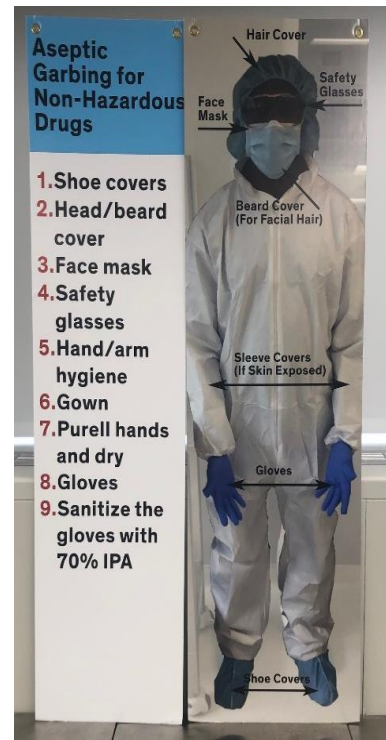
# UIC COP Lab – New Setup

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- 2 “modes”: non-sterile vs sterile
  - Sterile
    - Ante room
    - Hazardous compounding room
      - 8 biological safety cabinets
      - 1 compounding aseptic containment isolator
      - 7 integrated vertical laminar flow zone tables (used for non-hazardous compounding only)
    - Non-hazardous compounding room
      - 8 horizontal laminar air flow workstations
      - 3 integrated vertical laminar flow zone tables

# UIC COP Lab - Ante Room/USP 797

- Students must remove any garment not required for compounding prior to garbing
- Full garb required
- Hand washing
  - Glo Germ™ test
  - Wash hands and forearms for at least 30 seconds
  - Dry with low-lint wipes
  - Hands free sinks
- Line of demarcation



# UIC COP Clean Room

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# UIC COP Lab - Clean Room/USP 797

- Room design
  - Positive room pressure (simulated)
  - Epoxy paint
  - Coved corners on floors
  - Hands free doors
  - Pass through boxes
- Cameras in each PEC



# UIC COP Lab - Clean Room/USP 797

- Assume materials have been disinfected prior to being brought into the cleanroom
  - Must disinfect items when bringing into the PEC
- BUD's
- Sterile filtering
- Spray hands with 70% IPA when hands leave the PEC
- Quality control – visual inspection/inspection box





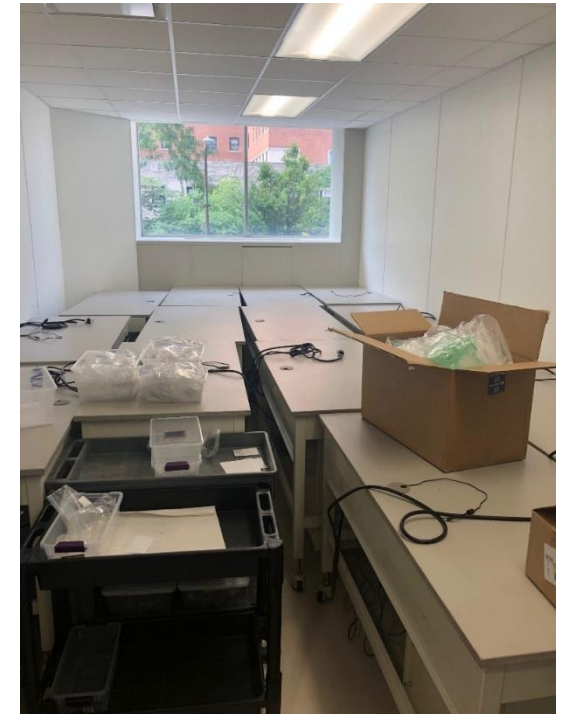
# USP 800

- Double garbing
- All work done in BSC's
- Negative room pressure (simulated)
- Closed System Transfer Devices (CSTD's)



# Limitations

- HVAC
  - ACPH
  - Externally vented PEC/room air
  - Negative/positive room pressure
  - ISO Class
- Space – dual use rooms
  - Removable walls and window coverings
  - Storage
- Room cleaning
- Cosmetics/artificial nails/piercings
- Hand washing
- Lack of lab time



# Questions?

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