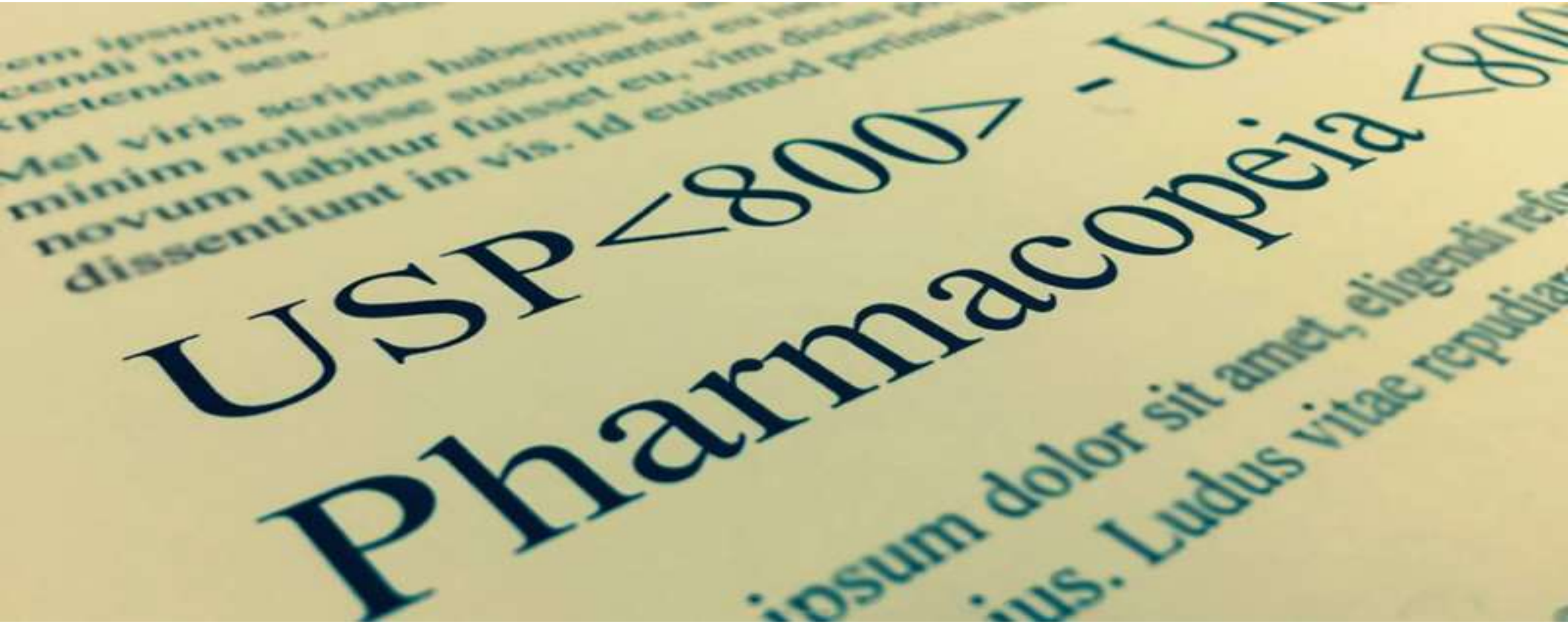
Focusing on Incorporating USP <800> Requirements



USP <800> Compliance

Deciphering USP 795/797/800 Requirements

- Implemented December 1, 2019
- USP 795
  - addresses non-sterile compounding
  - applied to skin or swallowed in pill form
- USP 797
  - addresses sterile compounding
  - injected into patients or inserted into their eyes
- USP 800
  - addresses hazardous compounding
  - customized meds in a controlled environment to maintain purity and avoid contamination

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Action Steps to Consider in Preparing for USP <800>

- Complete an assessment of risk
  - Check list for USP <800>

  www.readyfor800.com/download-ready-800checklist/
- Upgrade existing facility to meet standards
  - assemble the team
  - determine project scope and goals
  - planning and development
- Educate and train personnel
  - continuing cycle of training, assessment, and improvement keeping patients safe, themselves safe and our environment safe.

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Architectural Considerations

- Prefabricated cleanrooms vs site build-out
- Seamless flooring
- Drywall ceilings
  - Eliminate or minimize access panels
- Door sweeps/seals
- Pass-throughs (sealed)
- Sink locations
- Eyewash locations
- Power door operators

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Mechanical Design Features

» The entity's health and safety management system must include:

- A list of HDs
- Facility and engineering controls
- Competent personnel
- Safe work practices
- Proper use of appropriate Personal Protective Equipment (PPE)
- Policies of HD waste segregation and disposal

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Mechanical Design Features

» **Facility and Engineering Controls**

- Design to include input from the entity's:
  - Pharmaceutical Staff
    - Understanding the intent of the space
  - Facility Staff
    - Ventilation System – Existing or New Equipment
    - Control System

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Mechanical Considerations

» C-PEC – Containment Primary Engineering Control (Ventilation Device to minimize worker and environmental exposures)

- Bio-Safety Cabinets, Isolators, Hoods

» C-SEC – Containment Secondary Engineering Control (Room Requirements)

- Pressure Requirements (Room by Room)
- Air Changes Per Hour (ACPH) Requirements (Room by Room)
- HEPA Filtration Requirements
- Best Practices (By System)
- Design Example

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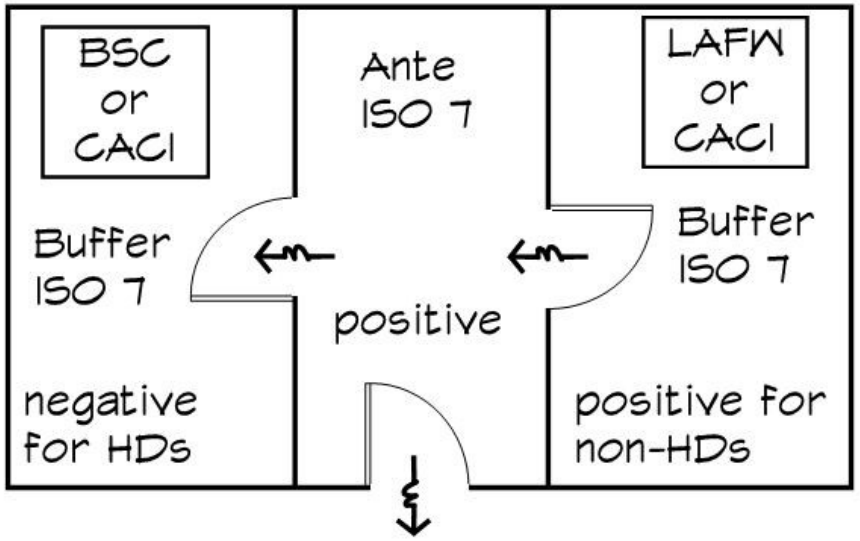
Mechanical Considerations

» **USP <800> Suggested Arrangement for Sterile HD Compounding Areas:**

» ISO Class 7

- 0.5 Micron Particle Size or Larger
- 10,000 Particles/Cu. Ft.
  - Class 10,000 Clean Room
  - Old System
- 352,000 Particles/Cu. Meter
  - New System



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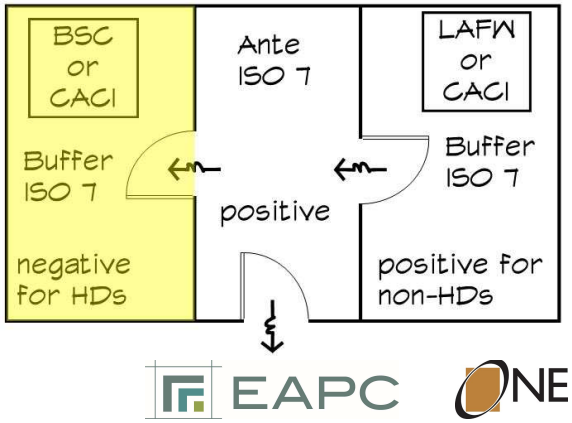
Mechanical Considerations – Room Requirements

» HD Sterile Compounding Room

- **Pressure Requirements**
  - Previous Requirement (USP <797>)
    - Negative – Minimum 0.01” wc (No Upper Limit)
  - New USP <800> Requirements
    - Negative – 0.01” wc – 0.03” wc
- **ACPH**
  - Unchanged at 30 ACPH minimum (Supply)
  - All air exhausted
- **Temperature & Humidity**
  - ≤68°F
  - ≤60% RH



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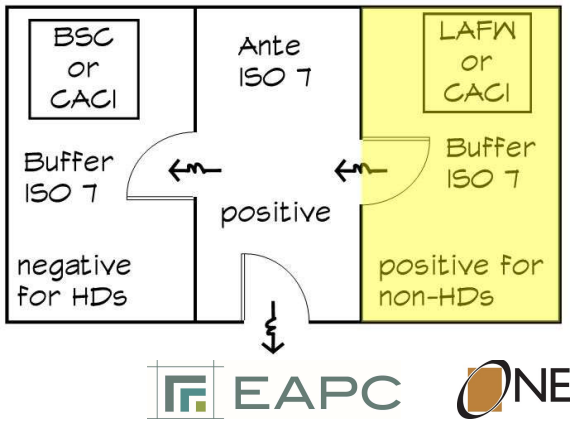
Mechanical Considerations – Room Requirements

» Non-HD Sterile Compounding Room

- **Pressure Requirements**
  - Previous Requirement (USP <797>)
    - Positive – 0.02” wc – 0.05” wc
  - New USP <797> Requirement
    - Positive – Minimum 0.02” wc (No Upper Limit)
- **ACPH**
  - Unchanged at 30 ACPH minimum (Supply)
  - Air can be returned (near floor)
- **Temperature & Humidity**
  - ≤68°F
  - ≤60% RH



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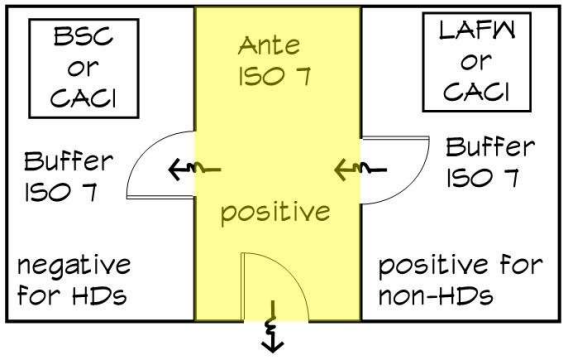
Mechanical Considerations – Room Requirements

» Ante Room

- **Pressure Requirements**
  - Previous Requirement (USP <797>)
    - Positive – 0.02” wc – 0.05” wc
  - New USP <797> Requirement
    - Positive – Minimum 0.02” wc (No Upper Limit)
- **ACPH**
  - Unchanged at 30 ACPH minimum (Supply)
  - Air can be returned (near floor)
- **Temperature & Humidity**
  - ≤68°F
  - ≤60% RH



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Mechanical Considerations – Room Requirements

» HD Storage Room

- **Pressure Requirements**
  - Negative – No Specific Pressure Range
- **ACPH**
  - 12 ACPH minimum (Supply)
  - All air exhausted
- **Temperature & Humidity**
  - ≤68°F (No Specific Requirement)
  - ≤60% RH (No Specific Requirement)

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Mechanical Considerations – HEPA Filtration Requirements

» HD & Non-HD Sterile Compounding Rooms & Ante Room

- **HEPA Filtration**
  - 99.97% for particles at 0.3 Microns and larger
  - Previous Requirements (USP <797>)
    - Could be located in Terminal Device, In Ductwork or at HVAC Equipment
  - New USP <797> Requirement
    - Located ONLY at Terminal Device (In Ceiling)

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Mechanical Considerations – Best Practices

» Central Ventilation System

- Existing System – Enough Fresh Air Capacity & Airflow
  - Utilize Fan-Forced HEPA Diffusers
- New Ventilation System
  - Fan-Forced or Regular HEPA Diffusers

» Airflow Rates

- Design for 35 ACPH

» Exhaust System

- Redundant Fans operating in Parallel
- Discharge minimum 10 ft above the roof

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Mechanical Considerations – Best Practices

» Pressure Control

- Pressure Independent Venturi Valve – CFM Offset
- Visual Pressure Indictors
  - Alarm - Visual and Audio

» Temperature Control Zones

- Control Zone for each Room
- Typically a Hot Water Terminal Coil

» Additional Considerations:

- Pressure Control in General Pharmacy Area
  - Active Differential Pressure Control
  - CFM Offset

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Electrical Considerations

» Emergency Power

- critical or equipment branch
- HEPA fan-powered filter modules
- chemo hood
- USP <800> room exhaust fan
- room pressure monitors
- sealed lighting fixtures
- refrigerators
- security system devices
- pharmacy equipment

Staff Support

Hazardous/ Non-Hazardous Sterile Prep

Pharmacy/Picking

Receiving

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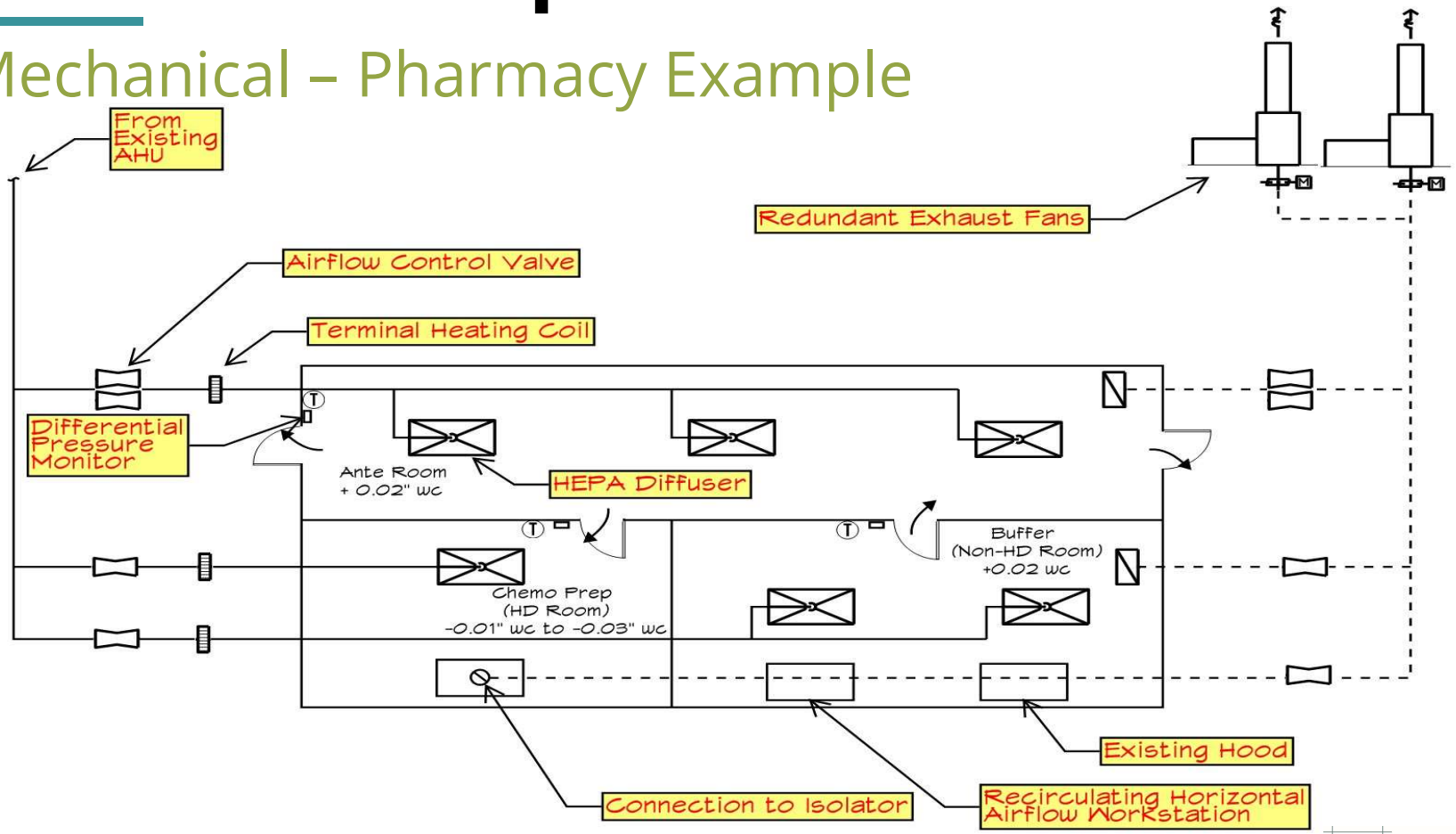
Mechanical – Pharmacy Example



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