Pharmacy Clean Room Design

TXCH Global HOPE

Texas Children's Hospital
CANCER AND HEMATOLOGY CENTERS

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Objectives

By the end of this presentation, the participant should be able to:

- Understand the purpose of a pharmacy clean room (buffer room) and ante room
- Define primary vs. secondary engineering controls in a pharmacy
- Describe important components of a pharmacy clean room

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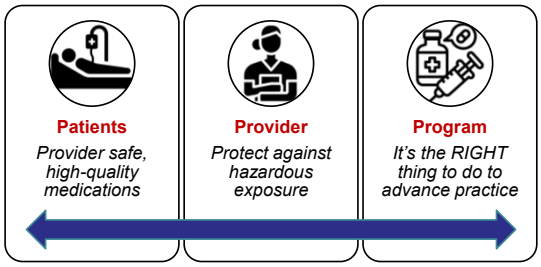
Why do we need a clean (buffer) room?



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Components of Clean Room Design

1. **Primary Engineering Controls**
   - Containment Primary Engineering Controls (C-PEC)
2. **Secondary Controls**
   - Containment Secondary Engineering Controls (C-SEC)
   - Containment Segregated Compounding Area (C-SCA)
3. **Supplemental Controls**
   - Closed system transfer devices (CSTDs)
   - Aseptic Technique Best Practices

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ISO 14644-1 Standards

ISO 5	ISO 7
• Less than 100,000 particles (of 0.1 µm each) per cubic meter (m^3) • Type of air which should be in the BSC • Also known as "Class 100"	• Less than 10,000,000 particles (of 0.1 µm each) per cubic meter (m^3) • Also known as "Class 10,000" • Type of air which should be in the ante room and buffer room

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Primary Engineering Control

C-PEC basics
- Externally ventilated device designed to minimize worker and environmental exposure to hazardous drugs
- Basically… it's the biosafety cabinet (BSC)!
- Provides ISO Class 5 or better air

C-PECs for sterile hazardous drugs
- Compounding aseptic containment isolator (CACI, or "glovebox")
- Class II, Type A2 or B2 BSC
- For preparation of injectables, intrathecals, etc.

C-PEC for non-sterile hazardous drugs
- Containment ventilated enclosure (CVE) or dedicated BSC
- For crushing oral tablets, preparing oral suspensions, etc.

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Secondary Control Components

Air changes per hour (ACPH)	• Minimum of 12 for C-SCA • Minimum of 30 for C-PEC
HEPA filtration	• HEPA = high efficiency particulate air • Traps particles greater than 0.3 micron in size • Become more efficient with time, but can also become contaminated with hazardous drugs or microbial organisms
Pressurization	• Negative pressure should be between 0.01 and 0.03 inches of water column relative to adjacent areas
Construction materials	• Durable, non-particle generating materials • Minimal lips, seams, corners, ledges

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Two "Types" of Pharmacy Spaces

ISO Class 7 buffer room + ISO Class 7 ante-room	Unclassified C-SCA
• Externally vented C-SEC • Negative pressure* • Externally vented C-PEC (Class II or CACI) • **30 ACPH**	• Externally vented C-SCA • Negative pressure* • Externally vented C-PEC (Class II or CACI) • **12 ACPH**

*Negative pressure should be between 0.01 and 0.03 inches of water column relative to adjacent areas

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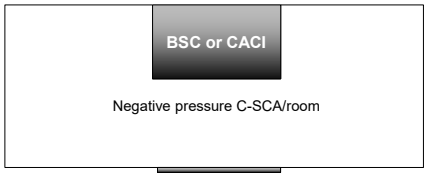
C-SCA Design Example

- For situations when a proper C-SEC design is not feasible
- Minimum of 12 ACPH



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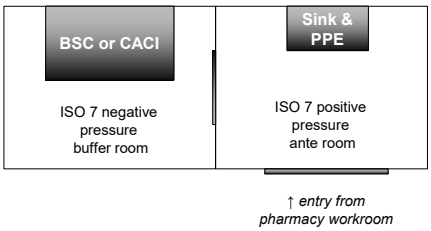
Ideal Buffer/Ante Room Design - A



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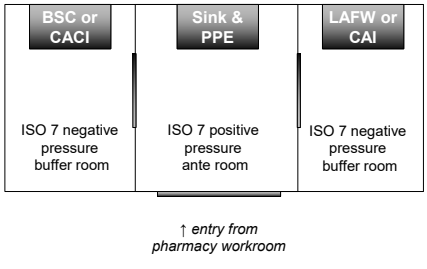
Ideal Buffer/Ante Room Design - B



BSC = biosafety cabinet, BSCII A2 or B2; CACI = containment aseptic compounding isolator; LAFW = laminar airflow workstation; CAI = compounding aseptic isolator

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Temperature and Humidity

- Ante and buffer room should be maintained at controlled room temperature
  - 20 to 25 degrees Celsius
- Relative humidity should be at or below 50%, with a goal of closer to 40%

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Other Considerations

- Location of personal protective equipment
- Sink location and method of activation (e.g., hands free)
- Location and type of waste disposal receptacles
- Secure access and remote monitoring
- Eye wash stations
- Refrigerators
- Shelving and storage
- Compounding pumps
- General office needs (phone, computer, chair, clock)

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What's Next?

- Read USP<800> if you have not done so already
- Complete the practice questions

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