Essentials of Aseptic Technique

Asepsis = the Absence of microorganisms, such as bacteria, fungus, and viruses.

1 in 31 hospital patients will develop a Healthcare-Associated Infection (HAI).

HAIs are potentially life threatening and kill thousands of people every year.

The five most common HAIs cost the US approx. $9.8 Billion per year.

These are not all from injectable compounded preparations.
Attitude Matters
when compounding sterile preparations

If you always keep in mind that there is a patient that will be injected with the compounded preparation you are mixing → Motivation

Why does a cleanroom have to be cleaner than an operating room?

Introducing Items into the PEC

Proposed USP <797>Section 8.2

• Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using low-lint wipers and allowed to dry before use.

• When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA.

• The wiping procedure must not render the product label unreadable.
Air directly from the HEPA filter in the hood is the cleanest; it has the lowest particle count of anywhere in the room. Sometimes referred to as FIRST AIR.

Bathe the critical site in FIRST AIR.

Avoid blocking FIRST AIR. Allow air flowing from the HEPA filter to remove contaminants introduced by personnel.

Poor technique can overcome the air flow direction and introduce reverse air currents that reintroduce contaminants into the hood.

Examples: quick movements, talking, coughing, sneezing, and leaning into the hood.

Poor placement of objects in the hood aseptic technique can also block the FIRST AIR.

A direct path must be maintained between the HEPA filter and critical sites

Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

First air: The air exiting the HEPA filter in a unidirectional air stream.
CRITICAL SITES require extra focus

Critical site:
- A location that includes
  - any component or fluid pathway surface (e.g., vial septa, injection ports, and beakers)
  or
  - openings (e.g., opened ampules and needle hubs)
- that are
  - exposed and
  - at risk of direct contact with
    - air (e.g., ambient room or HEPA filtered),
    - moisture (e.g., oral and mucosal secretions), or
    - touch contamination.

Dispensing pins
Vial stoppers
IV bag ports
Ampule necks
Syringe tips
Needles
Transfer devices
Syringe connectors
Tubing connectors

Unacceptable Place of Objects in the Hood

Objects
HEPA filter
Zone of turbulence

Not FIRST AIR
Not unidirectional air

By placing the objects in front of each other, the chance for contamination is increased as the airflow is being blocked.
Best Practices

Do not lean into or on the hood during compounding

Keep arms up off surface including edge

Keep head and shoulders out of the hood

Check manufacturers recommendations for particular equipment
Touch Contamination is the #1 Cause of CSP Contamination

Avoid touching any **CRITICAL SITE** including:

- Vial Stoppers
- Ampule necks
- IV bag ports
- Syringe tips
- Needles - all parts
- Transfer devices
- Dispensing pins
- Syringe connectors
- Tubing connectors

Syringe Selection and Use

- For best accuracy, use the smallest syringe that can hold the amount of solution needed
- However, use the 80% rule: When dispensing syringes, it is a good practice to only fill the syringe to approx. 80%, to avoid plunger drawbacks.

- Avoid using the same needle to draw up different medications
- Limit syringe and needle use to not more than ____ times
Suggested needle size selection guidelines

Limit needle use to not more than 3-5 times

<table>
<thead>
<tr>
<th>SYRINGE CAPACITY (ML)</th>
<th>NEEDLE GAUGE</th>
<th>NEEDLE LENGTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 3, 5</td>
<td>21 -20 G</td>
<td>1 inch</td>
</tr>
<tr>
<td>10, 20, 30, 35</td>
<td>18 – 19 G</td>
<td>1- 1 ½ inches</td>
</tr>
<tr>
<td>50, 60 (or viscous liquids)</td>
<td>16 G</td>
<td>1 ½ inches</td>
</tr>
</tbody>
</table>

NEEDLE RISKS

Coring
- The development of a core or hole in the rubber of a vial
- To prevent coring insert needle as shown
- Insert the bevel tip first, then pressing downward and toward the bevel so the bevel tip and heel enter at the same point
NEEDLE RISKS

Avoid recapping needles

Use a one-handed scoop method if needed

Report to management, follow SOPs

Vials and Ampules

- Vials are closed system containers
- For easier injection and withdrawal of fluids from the vial, equalize the pressure in the vial to the pressure outside the vial

  - Equalize the air pressure:
  - Inject air into the vial first before fluid withdrawal
  - For powdered drugs, inject the diluent, then withdraw an equal volume of air

- Ampules are usually made of glass
- Have a dot or stripe on the neck to indicate the weak spot for opening. Swab the neck, open to the side of the hood, away from HEPA filter. Use a filter needle
To inject fluid into a vial

If you just add the fluid, pressure builds!

Allow air to leave as fluid enters the vial.

Maintain equal pressures, so you don’t have to fight the vial.

To withdraw fluid from a vial

Inject portions of air as you withdraw fluid to equalize pressure.

Make sure the needle remains in the fluid.
Check, check, and check again

• Mix until completion, one batch or one patient’s medication at a time
• Keep talking to a minimum, maintain focus
• Use a triple check method. Check BEFORE compounding, Recheck during compounding, and Check again upon completion.

Remember the 4 Ds:
• Do I have the right DRUG?
• Do I have the correct DILUENT?
• Did I make the correct DOSE?
• Does it have the proper DURATION?

Not in USP<797>
UConn Best Practices

Best Practices for aseptic manipulation

• Items should be wiped down with sterile 70% IPA in the before entering the clean side of the ante room or pass through. Use gloves (not sterile).
• Gather all items needed for the compound; place only items needed to complete the task in the ISO 5 PEC
• Wipe down supplies again when placing in ISO 5 PEC
• Inspect supplies when wiping down to place in ISO 5 PEC
  • proposed <797> requires re-inspection at some point; this is a good point to assure re-inspection
• Maintain distance of ____ between objects
• Swab critical sites with sterile 70% IPA and allow to dry <797>
  • 3 times and away from the HEPA filter
• Open packages toward HEPA filter
• Avoid punching through paper packaging
• Move trash to the side of the hood
• Avoid moving in and out of hood
• Disinfect gloves every time you leave the ISO 5 air
On January 31, 2018, Pharmacy Technician(b) (6) was sterile processing TPN products in Hood(01) RX# (b) (6) I observed that (b) (6) consistently put the top of her head (exposing the skin from her neck and face) into the hood along with parts of her shoulders. I also noted on February 1, 2018, an instance in which(b) (6) left the ISO 5 hood for supplies in the ISO 8 area and upon her return to the ISO 5 (b) (6) neglected to change and/or sanitize her gloves prior to entry into the ISO 5 Hood. (b) (6) had processed RX#’s (b) (6) (b) (6) that day.