

# Definitions and Frequently Asked Questions Concerning Pharmacy Equipment

Provided by Germ Free

## COMPOUNDING ASEPTIC ISOLATOR (CAI):

A form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter (HEPA minimum).

## COMPOUNDING ASEPTIC CONTAINMENT ISOLATOR (CACI):

A compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

## UNIDIRECTIONAL FLOW :

An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area. (GERMFREE uses Unidirectional Laminar Airflow technology in our pharmacy equipment.)

## Questions & Answers:

**Q. When do I need to be compliant?** Now. It is important to understand that USP Chapter 797 is already in effect and has been since January, 2004. The original chapter has since been revised and that revision will replace the existing chapter in June 2008.

**Q. Are Barrier Isolators / Isolators / Compounding Aseptic Isolators CAI/CACI compliant with the USP 797 revision?** Yes. Provided they have unidirectional airflow and that HEPA filtered air shall be supplied in critical areas at a velocity sufficient to sweep particles away from the compounding area – even during operations. (The LFGI and VersaFlow by GERMFREE both utilize the principles of unidirectional flow and have been tested extensively both at the factory and in the field using smoke studies.)

**Q. Can an Isolator be used outside of a Cleanroom or Buffer Area?** Yes. Isolators that meet and exceed the three conditions imposed by USP 797 for operation outside of a classified space can be used outside of a cleanroom.

1. They provide isolation of the ISO Class 5 work space during transfer of items in and out.
2. The critical exposure site is always in ISO Class 5 air.
3. During material transfer less than 3520 particles greater than 0.5 microns in size were counted directly at the transfer door.

**Q. Can I use a Laminar Flow Workbench or Chemo Hood outside of a Cleanroom?** Typically no. There are two exceptions allowing the use of ISO Class 5 clean air equipment outside of a cleanroom.

1. Immediate-Use Compounded Sterile Preparation (CSP).
2. Low-Risk with a <12 hour Beyond-Use Date

Please see the full copy of USP <797> for more details on the conditions required to meet these two exceptions.

**Q. What are the requirements for using a Compounding Aseptic Containment Isolator (CACI), for Hazardous Drugs?** The surrounding space shall maintain a relative negative pressure of 0.01" water column and have a minimum of 12 air changes per hour. To achieve this negative pressure the CACI shall be in a segregated room- this room does not need to be a cleanroom. Negative pressure can be established by externally exhausting the CACI 100% to the outside. NOTE: There is a recommendation that the exhaust from CACIs is totally vented and that surface wipe samples are done periodically to ensure containment.

**Q. Do I have to Exhaust my CACI?** The CACI optimally should be 100% vented to the outside air through HEPA Filtration. (The GERMFREE LFGI Series can be vented to the outside.)

**Q. Can I still use my current Chemo Hood?** Yes, if it is inside a negative pressure ISO Class 7 cleanroom. It is the recommendation that the exhaust from the chemo hood be totally vented. The act of externally venting of the hood assists in making the whole room negative.

**Q. What do the users of CACIs need to wear when compounding hazardous drugs?** Personal Protective Equipment should be worn when handling and compounding hazardous drugs. (The level of personal protection recommended by GERMFREE is a gown, eye protection, head / facial hair covers and double gloving with chemically resistant gloves.)

**Q. What supplies do I need to use with my Isolators, Laminar Flow Workstations or Chemo Hoods?** Sterile 70% IPA will be used to disinfect gloves, work areas and supplies. Sterile gloves are now required. Sterile water for injection or irrigation for the removal of water soluble solid residues during the cleaning process. Non/Low-shedding wipers or sponges for cleaning and disinfecting.

**Q. How often do I need to clean my clean air equipment?** USP <797> requires disinfection happen before each batch, every 30 minutes, after spills and when contamination is suspected. You must allow 30 seconds contact time and the IPA to evaporate before compounding. (GERMFREE recommends a thorough cleaning and disinfecting of the work area at the beginning of each shift.)