

## Ongoing Training for Sterile Compounding

Ongoing training for sterile compounding must be completed, passed and documented at least every 12 months (hereafter annually) for low and medium risk compounding and at least every 6 months (hereafter semi-annually) for high risk compounding. This training must be for the appropriate risk level the compounding personnel will face. The ongoing training that is required by USP Chapter 797 is as follows:

1. Documentation of all compounding personnel passing a written exam. This must be done annually for low and medium risk compounding and semi-annually for high risk compounding. The exam must include questions testing, at a minimum, the following areas: hand hygiene and garbing; aseptic technique; and cleaning and disinfecting.
2. Documentation of a visually observed cleaning and disinfecting competency. This must be done annually for low and medium risk compounding and semi-annually for high risk compounding. The documentation must include visual observation of the cleaning and disinfecting of the primary engineering control (hood or isolator) and the ante and buffer rooms, as applicable. Environmental Services must be trained as well if they clean or disinfect the ante and buffer rooms. Environmental Services is not allowed to clean or disinfect the primary engineering control.
3. Documentation of all compounding personnel passing a visually observed hand hygiene and garbing competency. The hand hygiene and garbing competency must be performed annually for low and medium risk compounding and semi-annually for high risk compounding.
4. Documentation of all compounding personnel passing a media fill challenge which evaluates aseptic technique. The media fill challenge must be performed annually for low and medium risk compounding and semi-annually for high risk compounding. The media fill challenge is to encompass the most challenging conditions the compounding personnel will face. The following documentation is required: media selection; fill volume; incubation time and temperature; inspection of filled units; interpretation of results; actions levels; and corrective action, if needed.
5. Documentation of all compounding personnel passing a gloved fingertip sampling. Gloved fingertip sampling must be performed annually for low and medium risk compounding and semi-annually for high risk compounding. Unlike the initial gloved fingertip sampling, which demonstrates the ability of compounding personnel to appropriately don sterile gloves, the annual/semi-annual gloved fingertip sampling is used to validate aseptic technique, therefore, it must be completed at the conclusion of the media fill challenge. Sterile 70% isopropyl alcohol is not to be sprayed on the sterile gloves immediately before the sampling. The fingertips and thumbs of both hands must

be tested. Two separate agar plates (paddles are not recommended) are to be used; one agar plate for each hand. A passing result is no more than 3 colony forming units (CFUs) total for both hands, not per agar plate.

Any compounding personnel who fail written or observed testing are to be immediately instructed and reevaluated by trained compounding personnel to correct deficiencies. Documentation of this instruction is required.