

# USP <797> Quiz

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1. **1. It is generally acknowledged that \_\_\_\_\_ of critical sites of CSPs (Compounded Sterile Preparations) with contaminants, especially microbial sources, poses the greatest probability of risk to patients.**
    - a) ISO Class 8 air exposure
    - b) ISO Class 7 air exposure
    - c) ISO Class 5 air exposure
    - d) Direct or physical contact
  
  2. **The 4 specific categories of CSPs described in USP <797> are:**
    - a) Low-risk, Medium-risk, High-risk, and Temporary-use
    - b) No-risk, Medium-risk, High-risk, and Ultra-high-risk
    - c) Low-risk, Medium-risk, High-risk, and Immediate-use
    - d) Low-risk, Medium-risk, High-risk, and Media-fill
  
  3. **The standards of USP chapter <797> are intended to apply to \_\_\_\_\_**
    - a) Compounding pharmacies only
    - b) Hospitals only
    - c) PCAB accredited pharmacies only
    - d) All persons who prepare CSPs and all places where CSPs are prepared
  
  4. **A room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is into the room is called a \_\_\_\_\_.**
    - a) Positive Pressure Room
    - b) Negative Pressure Room
    - c) Ante Room
    - d) Buffer Room
  
  5. **Passage of a fluid or solution through a sterilizing grade membrane to product a sterile effluent is \_\_\_\_\_.**
    - a) Terminal sterilization
    - b) Autoclaving
    - c) Incubation
    - d) Sterilized by filtration
  
  6. **If a Multi-dose drug vial (with preservatives) is used to prepare a compounded sterile preparation, the vial must be used within \_\_\_\_\_.**
    - a) 30 days
    - b) 14 days
    - c) 9 days
    - d) 28 days
  
  7. **According to USP <797>, the recommended action level of CFUs for a surface sample in the ISO Class 5 Primary Engineering Control is \_\_\_\_\_ .**
    - a) > 3
    - b) > 5
    - c) not defined
    - d) zero, no contamination is permitted
  
  8. **After the garbing procedure, but before donning sterile gloves, all personnel must use \_\_\_\_\_ .**
    - a) Sterile Isopropyl Alcohol on hands
    - b) A waterless, alcohol-based surgical hand scrub
    - c) A clean handkerchief
    - d) A hand sanitizer (like Purell)
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