

## Revisions to USP Chapter <797>: Examining Sterile Compounding Practices

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**There are 10 questions associated with this study guide.**

1. Which of the following describes the process followed by the USP Sterile Compounding Expert Committee during the revision of USP chapter <797>?
  - a. Revision process began 6 months prior to publication.
  - b. The committee reviewed over 1000 pages of comments from practitioners, experts, and advisory groups.
  - c. USP Chapter 797 is final and will not need another revision.
  - d. The introduction to chapter 797 was not revised.
2. Which of the following sections in chapter <797> was NOT added or significantly changed?
  - a. Environmental sampling and controls.
  - b. Allergen extract compounded sterile preparations (CSPs).
  - c. Packing and transporting CSPs.
  - d. Definitions section.
3. Pharmacists and pharmacy personnel need to understand the process of the USP Sterile Compounding Expert Committee and adhere to the revised standards of USP chapter <797> because:
  - a. Direct contact and poor compounding practices have been identified as the primary sources of contamination in CSPs.
  - b. USP chapter 797 is primarily a working manual for cleanrooms and isolators.
  - c. Adherence to chapter 797 is required by boards of pharmacy in fifty states.
  - d. Sterile preparations no longer require environmental controls when prepared in a compounding aseptic isolator (CAI).
4. Which of the following is correct according to revised <797> immediate-use category requirements?
  - a. Hazardous drugs are included in the immediate-use exemption as long as not more than 3 transfers are required.
  - b. Administration of immediate-use preparations must begin within 1 hour of the start of compounding.
  - c. The immediate-use category eliminates the need for a laminar flow hood or isolator for compounding chemotherapy.
  - d. Preparations compounded for immediate use may be stored overnight for use within 24 hours after compounding.

5. When assigning beyond-use dating for single and multiple-dose vials, which of the following is correct?
  - a. Single-dose vials opened or punctured in ISO 5 environment may be used up to 96 hours.
  - b. Single-dose vials opened or punctured in ISO 7 environment may be used up to 96 hours.
  - c. Ampules opened in ISO 5 environment may be used for up to 96 hours.
  - d. Multiple-dose vials opened or punctured in ISO 5 environment may be used up to 28 days unless specified otherwise by the manufacturer.
  
6. USP chapter <797> revised requirements pertaining to hazardous drugs, including cancer chemotherapy, include which of the following?
  - a. Compounding should be performed in a biological safety cabinet or compounding aseptic containment isolator (CACI) located in a separate negative airflow ISO 7 buffer room with an ISO 7 ante area.
  - b. Closed-system vial transfer devices provide a suitable substitute for biological safety cabinets and compounding aseptic containment isolators.
  - c. The requirements of chapter 797 are to be followed when compounding hazardous drugs regardless of the number of doses being prepared each week.
  - d. Protective garb for personnel is not required when compounding is performed in a biological safety cabinet.
  
7. USP chapter <797> outlines cleaning and disinfection frequencies for sterile compounding facilities. Which of the following cleaning and disinfection schedules is NOT correct?
  - a. Clean and disinfect floors daily.
  - b. Clean and disinfect walls and storage shelves monthly.
  - c. Clean and disinfect work counters daily.
  - d. Clean and disinfect laminar airflow workbenches daily after compounding.
  
8. Personnel cleansing and garbing standards require staff education and certification to maintain aseptic compounding conditions. Which of the following is correct?
  - a. Remove outer garments and any jewelry except piercings.
  - b. Don protective lint-free gown before shoe covers.
  - c. Cleansing, garbing, and gloving requirements also apply to compounding in CAIs and CACIs.
  - d. Apply nonsterile isopropyl alcohol to contact areas of gloves as needed.
  
9. Environmental controls are aimed at creating ISO 5 and 7 environments. These controls should be:
  - a. Tested during dynamic conditions.
  - b. Tested during installation and annually.
  - c. Located in an area accessible to all pharmacy personnel.
  - d. Located in an area with access to outside air.
  
10. The microbiological beyond-use date for a medium-risk CSP stored in the refrigerator is:
  - a. 3 days.
  - b. 7 days.
  - c. 9 days.
  - d. 14 days.