

Is Your Practice USP 797 Ready?

Mohamed Yassin, MD, FAAAAI, offers the following tips

The following information will be helpful for you and your office in fulfilling the USP requirements:

1. Demonstrate required personnel qualifications - this will take longer than figuring the USP physical requirements. Your compounding staff must [complete training](#) before starting compounding (i.e. written exam, gloved fingertip, and thumb sampling X3 [three different days], media fill test).
2. Keep records of staff training and in-house certification.
3. Order appropriate size sterile powder-free gloves, gowns (consider reusable gowns) for your staff and practice hand hygiene and garbing.
4. Create a log of all your existing extracts and diluent; manufacturer, lot number, strength, expiration date and update information when you receive new extracts in the future.
5. Create [extract compounding log](#).
6. Create [Standard Operating Procedures](#) for extract mixing. Comply with [cleaning procedures](#).

Regarding the USP 797 physical requirements, if you haven't decided yet, you have the choice either the [AECA or the ISO class 5 PEC](#).

If you decide on AECA, this is important to know:

1. The walls (and ceiling) must be washable with EPA approved one step cleaning / disinfecting agent. Unfortunately, such cleaning agents work only on non-porous walls. Regular wall paint, oil-based paint or latex paints have porous surfaces.
2. You will need to remove the existing paint, apply epoxy paint, or apply acrylic concrete stain as primer.

Iso Class 5 PEC:

1. Horizontal ISO class 5 PEC are easier to use and maintain than the Vertical PECs
2. Enquire about maintenance and recertification before purchasing.
3. Ask your local hospital pharmacy what company they use to recertify their PECs.