

Other Key Terms Related to USP 797

To successfully navigate the requirements of USP 797, you need to become familiar with some essential terms:



ISO

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO is an international non-governmental organization that establishes standards for various industries and countries. Its name, derived from a Greek word meaning "equal," reflects its commitment to ensuring consistency across languages and borders.

ALLERGENIC EXTRACTS COMPOUNDING AREA

AECA refers to a designated space with a visible perimeter that meets the necessary criteria for mixing allergenic extracts.



AECA



PEC

PRIMARY ENGINEERING CONTROL

If you don't have an AECA, you'll need a PEC with an ISO class 5 ventilation hood, to maintain the required sterility.

COMPOUNDED STERILE PREPARATION

This term encompasses the standards and guidelines for maintaining cleanliness and ensuring sterilization during the preparation and administration of extracts, aligning with the rules for storing, making, and administering injections.



CSP



BUD

BEYOND USE DATE

The BUD for a prescription set must be no later than the earliest expiration date of any allergenic extract or diluent within that prescription set. It must not exceed one year from the date the prescription set is mixed or diluted.

STANDARD OPERATING PROCEDURES

SOPs are sets of clear, written instructions for performing routine tasks. Strict adherence to these procedures is crucial for maintaining compliance with USP 797 regulations.



SOP

As the implementation date of USP 797 draws nearer, it's essential to equip yourself with the knowledge and understanding of these key terms and concepts. These terms will serve as your guide as you diligently prepare to meet the new standards on November 1, 2023.