USP <797> Overview

The new USP <797> guidelines are designed to prevent the improper handling and contamination of sterile compounds for certain drugs or biologic preparations. These items include:

1. Baths for live tissues and organs
2. Opthalmics
3. Parenterals
4. Tissue implants
5. Aqueous nasal and bronchial inhalations
6. Irrigating solutions

The guidelines impact not only the people who prepare the compounded sterile pharmaceuticals (CSPs) but also the areas where theses drugs are prepared and stored including commercial and hospital pharmacies, clinics, doctor's offices and other facilities. USP <797> recommends certain clean area designs, storage specifications, environmental monitoring plans, and employee training programs to accomplish the safe handling of these preparations. These guidelines specifically address:

1. Microbial contamination
2. Endotoxins
3. Physical or chemical contamination
4. Preparation of incorrect concentrations
5. Incorrect ingredients

A mistake in any of these 5 areas may cause serious injury or even death.

While a good portion of the USP <797> guidelines deal with improving air quality in these facilities, an equally important goal is to prevent contamination of these preparations during manufacture. Products are manufactured according to risk levels: low, medium or high. Products that are to be injected carry the greatest risk of serious health effects; therefore these products must be manufactured in an area having the lowest risk level for contamination. The lowest contamination risk level required under USP <797> for a critical area is an ISO Class 5 area designation.

The design of Class 5 preparation areas and Class 7 buffer areas surrounding them, is a requirement. Semi-annual monitoring for viable bacteria and fungi in air, gloved fingertip, surface contact plates, and particulates is required for both Class 5 and Class 7 designated areas. These monitoring results trended over time will provide information on any deterioration in air quality and aseptic technique. Generally, this monitoring should be conducted semi-annually.

The action levels for microbial and particulate monitoring results are summarized below:

Semi-Annual Microbial and Particulate Monitoring

ISO Clean Room Classification	Particulate Count FS 209E (> 0.5 µ/ft^3)	Particulate Count ISO (> 0.5 µ/m^3)	Air Sampling 400-1000 L (CFU/m^3)	Gloved Fingertip Sampling Total (CFU/Plate)	Swab/Surface Contact Plate (CFU/Plate)
Class 5	100	3520	>1	>3	>3
Class 7	10,000	352,000	>10	NA	>5
Class 8	100,000	3,520,000	>100	NA	>50

One important item should be noted. Regardless of the number of CFUs recovered, corrective actions are required if any pathogenic organisms or molds are identified. Therefore, when any colonies are seen on the plates, those colonies must be identified to at least the genus level to determine the presence of pathogens.