USP 797

New requirements include proper facility design, environmental monitoring, handling and storage of sterile compounds to prevent serious illness or fatalities caused by accidental contamination.

The Joint Commission is enforcing the USP 797 chapter on Sterile Preparations. Full compliance with the regulations was targeted for January 2008. These new requirements include the proper facility design, environmental monitoring, handling and storage of sterile compounds to prevent serious illness or fatalities caused by accidental contamination of these materials. 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:

- Baths for live tissues and organs
- Tissue implants
- Aqueous nasal and bronchial inhalations
- Irrigating solutions
- Opthalmics
- Parenterals

While a good portion of the USP 797 guidelines pertain to improving air quality in these facilities, an equally important goal is to prevent physical contact with and 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 risk level required under USP 797 for a critical area is an ISO Class 5 area designation.

The design of Class 5 clean areas for preparation and Class 7 buffer areas, surrounding Class 5 areas, 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.

ACTION LEVELS FOR SEMI-ANNUAL MICROBIAL AND PARTICULATE MONITORING

US Clean Room Classification	US Clean Room Classification ($0.5\ u/ft^3$)	Particulate Sampling $0.5\ u/m^3$	Air Sampling 400 -1000 L* CFU/m^3	Gloved Fingertip Sampling Total CFU/Plate	Swab/Surface Contact Plate Sampling CFU/Plate	Endotoxin (frequency depends on CSP batch numbers/ storage conditions)
Class 5	100	3520	>1	>3	>3	See USP monographs
Class 7	1000	352,000	>10	NA	>5	See USP monographs
Class 8	10,000	3,520,000	>100	NA	>100	See USP monographs

** Based on sampling rate of 100 lpm*

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

NATIONWIDE LOCATIONS

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, Quality Assurance plans which include environmental monitoring, and employee training programs to accomplish the safe handling of these preparations.

These guidelines specifically address: Microbial contamination; Endotoxins; Physical or chemical contamination; Preparation of incorrect concentrations and incorrect ingredients. ***A mistake in any of these 5 areas may cause serious injury or even death.***

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