

Understanding USP 797

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Understanding USP 797

- ☞ The purpose of USP 797 is to prevent harm and fatality to patients that could result from microbial contamination and excessive bacterial endotoxins. The regulations apply to healthcare institutions, pharmacies, physicians offices, and other facilities where compounded sterile preparations (CSPs) are prepared

Understanding USP 797

- CSPs include the following types of preparations:
- Those prepared according to the manufacturer's label instructions that expose original contents to potential contamination.
- Those that must be sterilized before administration.
- Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that include baths and soaks for live organs, implants, inhalations, injections, and powders for injection, metered sprays, and ophthalmic and optic preparations.

Understanding USP 797

- Hospital pharmacies are struggling with compliance to USP 797.
- The ranges of issues encompass everything from Clean Room infrastructure design to demanding quality requirements.
- Use Sterile Compounding Isolators

Understanding USP 797

- ☞ The United States Pharmacopeia (USP) states, “It is the ultimate responsibility of all personnel who prepare CSPs to understand these fundamental practices and precautions, to develop and implement appropriate procedures, and to continually evaluate these procedures and the quality of final CSPs in order to prevent harm and fatality to patients who are treated with CSPs.” Sterile compounding practices are now enforceable by both the Food and Drug Administration (FDA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The FDA will not directly inspect the pharmacies, but JCAHO compliance with 797 is required by all pharmacies.

Understanding USP 797

- ☞ Personnel must be proficient in the principles and practices of aseptic manipulations, and have knowledge of sterilization and stability. In order to perform these responsibilities in a consistent manner, a sterile compounding pharmacy must provide its personnel with well-designed Clean Room facilities and equipment Compounding Isolators, validated procedures, sterile disposables, expert training, and independent quality review. This is the true focus of USP 797.

Understanding USP 797

☞ **Cleaning and sanitization**

- ☞ Cleaning and sanitization must follow written procedures, and are the responsibility of the pharmacists and technicians. Cleaning and sanitization is performed at the beginning of each shift and include horizontal surfaces, floors, walls, carts, and shelving. Work surfaces near the compounding area should be disinfected more frequently. Approved agents must be used to perform all cleaning and sanitization. In addition, cleaning logs must be kept. Non-shedding wipes, sponges, and mops are to be used, and appropriate contact times should be observed. And, a rotation of disinfectants is advisable.

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- **Personnel cleaning and gowning**
- If using a Clean Room all personnel should be trained and educated in contamination-control principles. Written procedures in the form of Standard Operating Procedures (SOPs) are required. Personnel should not wear makeup or jewelry, and hands and arms should be completely covered. Hair covers, disposable lab coats, shoe covers, and gloves must be worn. Routine re-sanitization of gloves should be frequent and performed upon re-entry into the sterile field. Personnel are advised to change into new Clean Room garments upon each entry.
- If using a compounding isolator this requirements don't apply.

Understanding USP 707

☞ Personnel training

- ☞ Training should be performed by expert personnel, and should be in the form of audio-video instruction and classroom instruction. All personnel must demonstrate an understanding of contamination control, media-fill proficiency, and gowning certification, Compounding Isolator use before being allowed to perform sterile compounding activities.

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ISO Classification of Particulate Matter in Room Air (limits are in particles 0.5μ and larger per cubic meter [current ISO] and cubic feet {former Federal Standard No. 290E, FS 209E])

Class Name		Particle Count	
ISO Class	U.S. FS209E	ISO m^3	FS209E ft^3
3	Class 1	35.2	1
4	Class 10	352	10
5	Class 100	3,520	100
6	Class 1,000	35,200	1,000
7	Class 10,000	352,000	10,000
8	Class 100,000	3,520,000	100,000

Understanding USP 797

- ☞ We at DDK Scientific address the customer's needs by providing Aseptic Compounding Isolators, Clean Benches and Clean Rooms

Understanding USP 797

Compounding Aseptic Isolator (CAI)

A form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator through the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air first passes through a microbial retentive filter (HEPA minimum)

Source: USP 797 Definitions

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Clean Room

A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

Understanding USP 707 Compounding Aseptic Isolator (CAI)



Understanding USP 797

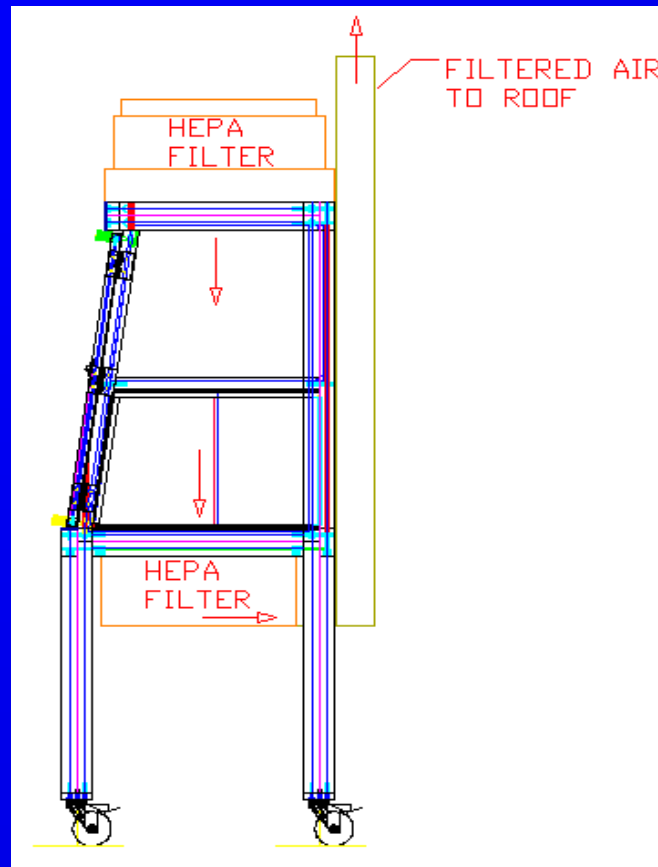
Compounding Aseptic Containment Isolator (CACI)

A compounding Aseptic Containment Isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

Source: USP 797 Definitions

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Compounding Aseptic Containment Isolator (CACI)



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Conclusion

The current USP 797 regulations emphasize the need to maintain high-quality standards for processes, components, and environments for sterile compounding preparations. The benefits of USP 797 compliance include the minimization of contamination of CSPs, improved aseptic proficiency of hospital pharmacy personnel, and increased drug quality levels. These benefits should translate into lower noscomial infection rates and overall better patient care.

Thank You



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