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USP 797 & 800 Compounding Pharmacy

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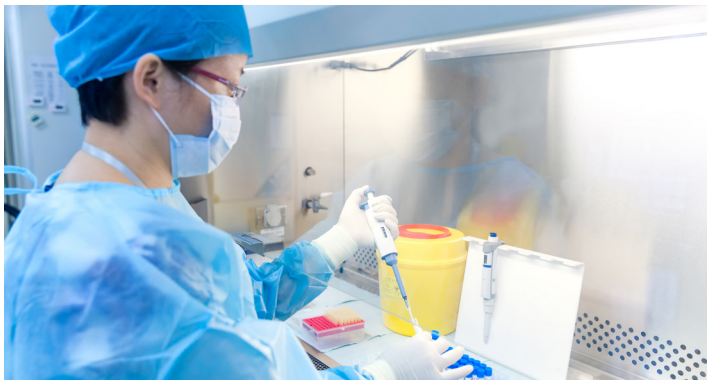

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USP 797 & 800

The types of pharmacies in a typical hospital

There are two types of pharmacies in the typical hospital. There is the one which you are already familiar that resembles a store. The other is called a “compounding pharmacy” and is not at all like the store. The compounding pharmacy is an isolated and stringently monitored laboratory where the hospital prepares the formulations or “compounds” used for the parenteral treatment of patients. Parenteral means to be injected intravenous, intramuscular, or subcutaneous and these medicines come with their own dangers and concerns.

These laboratories also formulate hazardous drugs such as chemotherapy or radiopharmaceuticals.

Buffer Area rated ISO 7 with HEPA Filters and SAF fixtures in the ceiling. NOTE: Pass through in center.

Compounding Pharmacy Dangers

Since these medicines are mixed and dosed to create IV solutions specifically for the patient and how they are administered, they must be kept strictly sterile. Pharmaceuticals that enter intravenously do not have the same level of assistance from the immune system.

In recent years, some newer treatments have emerged that go beyond traditional chemistry and are more like portions of once living materials. These are generically called biologics and must be protected from the usual sterilization chemicals or processes common for non-viable pharmaceuticals.

What is the USP?

The United States Pharmacopeial Convention (USP) is a non-profit scientific organization founded in 1820 in Washington, D.C., that develops and disseminates public quality standards for medicines. USP’s primary compedia of standards are the United States Pharmacopeial and the National Formulary (USP-NF) which are widely accepted as the authority regarding drug safety.

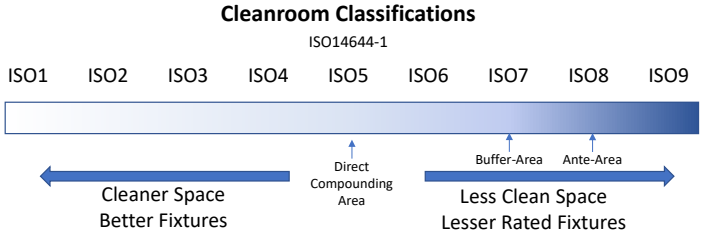
Concerns

These lab spaces formulate medicines for many patients each day and the base materials are many times more potent than what is given to the patient. Consequently, these concentrated base materials must be carefully handled in order to ensure proper dosing. A single small grain of, say a chemotherapy medicine, finding its way into another patient’s dose could have catastrophic results.

Similarly, if it is bad for the patient then what about the custodian or maintenance personnel who might, during a cleaning cycle, be exposed to a unique concoction of whatever is handled in that laboratory.

Regulation:

There are numerous oversight authorities such as OSHA, the Joint Commission along with national and local governments involved in regulating hospitals and specifically the hospital pharmacy space. When it comes to pharmaceuticals however, most of these authorities look to the USP for recommended practices for the safe handling of pharmaceuticals.



USP 797 & 800

USP797 relates to sterile drugs. USP800 is about hazardous drugs. Both need to be handled within a properly designed compounding pharmacy. Much like traditional Clean Rooms, under USP797 and USP800, maintaining a sterile field surrounding the entire compounding process requires a careful control of room air path and flow.

Within the overall design of these spaces, there are typically 3 areas to consider; Each room in the path gets cleaner as you get closer to the compounding process. The first room is called the Ante-area: this is where preparation such as garbing and gloving as well as staging and computer work is performed. These spaces should be designed and tested to at least ISO-8 according to ISO14644-1 standards. The next space is called the buffer area and is ten times cleaner with at least 30 air changes per hour and an ISO-7 cleanroom classification.

The third area is in the direct compounding area and needs to be rated ISO-5 or cleaner to maintain purity. Air needs to be supplied from HEPA filters through ductwork located in the ceiling. Return air needs to exit the room through wall mounted registers near the floor. This creates a washing effect. The vertical flow of air keeps particles from accumulating and washes them out of the room through the shortest and best path.

Each area in the laboratory can be separated by a wall with a pass-thru or door. The compounding work is typically done in a BSC hood or laminar flow workbench with HEPA filtration.

Most of the fixtures used in a compounding pharmacy are going to be recessed. This presents the least number of surfaces that need cleaning. Of course, there may also be task lights and teardrop shaped laminar flow lights in the hood, however the common lighting will be recessed.

IES Recommended Illuminance	
Laboratory	Recommended Illuminance (fc)
Ante-Area & Buffer	100* (1000 lux)
Direct Compounding Area	150* (1500 lux)
*Values based on maximum of multiple sources	

When it comes to selecting a fixture for a compounding pharmacy you should look for these features:

1. A single progressive surface exposed to the room. Most manufacturers call this an overlapping door. Look for doors with a beveled angle where it transitions to the ceiling. This makes wipe down cleaning more complete, keeping particles out of the corners between surfaces. The bevel should be welded and smooth.
2. An NSF2 listed construction. The NSF evaluates a fixture for construction methods and materials compatible with maintaining cleanability over time. Even though the standard is based on food it is applicable here too.
3. Corrosion resistant materials such as type 304 stainless steel should be used where the cleaning process might include the typical alkali sterilizing solutions. If acidic solutions are in use opt for type 316 stainless steel.
4. Captive countersunk flush screwheads prevent the tearing of wipers during the cleaning process. You need the screws so don't specify a fixture that does not use screws to hold the door closed. (Cleanroom air pressures can easily overcome other fixture closing mechanisms)
5. Make sure that the lighting is up to the minimum IES standard for illumination. The current RP-29-16 recommends 150 fc (1500 lux) for the compounding area. We recommend 100 fc for the Ante and Buffer areas. Also consider using high color rendering LED sources greater than 80 CRI. The work done in these labs often references color. Some chemicals are photosensitive to blue light. For these areas we recommend having a dual purpose, white and amber LED fixture so that when handling photosensitive pharmaceuticals, the light can be changed to a safe amber spectrum.
6. Recessed fixtures should be designed for the type of ceiling used. Often these cleanrooms will have hard ceilings and require a flanged cleanroom fixture. Using a lay-in fixture in a ceiling adapter is a sure way to fail a cleanroom certification. The air pressures of these small cleanrooms can displace fixtures that are not mechanically secured or clamped in place. So, look for fixtures that have swing style mounting brackets for hard ceilings.
7. Choose a fixture that is rated for use in your cleanroom. Cleanroom ratings are in a reverse order, with the best and most capable fixtures are rated with the lower numbers. So, an ISO-7 cleanroom is also covered by an ISO3 or ISO5 rated fixture. This rating is important and cannot be overlooked but the previous 6 other criteria are at least as important as the cleanroom rating.
8. As an assurance of a good seal, choose a fixture with an IP65 or IP66 certification. This standard includes a rigorous test for dust penetration and that is exactly the kind of resistance needed here.

Our recommended products:

SAF for Compounding and Buffer Areas
CRTD for Laminar Flow areas CRU for Ante-areas.

SAF

CRTD

CRUi

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