# Design Your Cleanroom to Ensure Easier Use, Cleaning, and Maintenance

Photo courtesy of Modular Cleanrooms.

**By Kate Douglass**

NUMEROUS ARTICLES HAVE BEEN WRITTEN REGARDING ENGINEERING considerations in the design and build of cleanrooms[1,2]. This article is written to share some insights gained over the last 5 years through the design, build and use of several USP <797> compliant pharmacy cleanroom complexes. It will provide pointers, hopefully not elsewhere reported, which can be added to other information gained from consultation with cleanroom engineers, builders, and other experts. Pharmacy cleanroom engineers can and do provide excellent guidance to pharmacists building new complexes or reengineering their current operations. However, little guidance exists for pharmacists who want to incorporate the practical aspects of cleanroom design that make using, maintaining, and cleaning a cleanroom easier. To get the best return on your investment, it is vital to build a complex that facilitates employee training, cleaning, environmental monitoring, product handling, and physical-plant maintenance.

## Facility Design Criteria Document

Ideally, the cleanroom layout should be based on a facility design criteria document, which is created using the risk-level matrix for compounded sterile preparations (CSPs) that are made (or will be made) at that specific facility, as well as USP <797> and state board of pharmacy requirements. A gap analysis comparing USP <797> requirements to your actual practices, policies, and procedures should be performed, and from that gap analysis, an action plan can be developed.

By developing the CSP risk-level matrix, it is possible to determine your specific needs based on practice in your setting and to consider alternatives for components, compounding methodologies, workload shifts (from unit to pharmacy), and outsourcing opportunities. With a valid risk-level matrix in hand, the facility design criteria document can be developed based on USP <797> and state board of pharmacy requirements. This document is fundamental to driving the evaluation of vendors. The vendor selected should receive the document and acknowledge in writing that their proposal will result in the achievement of the stated functional criteria. ***(To view a sample facility design criteria document, visit www.pppmag.com/articles.php.)***

Cleanroom design is complicated and many small decisions are made along a cleanroom's journey to completion. By taking the time to detail your requirements in a design criteria document, you will likely encounter fewer surprises along the way. You will also have a way to hold the vendor accountable. This document should drive design and engineering meetings, and any changes or additions made along the way should be documented in writing.

## Assuring Administration's Buy-in

In making your case to administration, it is recommended that you develop a white paper which lays out the rationale for the recommended changes to your facility. To be effective, the white paper should address the following areas:

- Regulatory and accreditation considerations for the proposed expenditure
- Quality improvement in patient safety and risk management (and lessened potential for litigation)
- Fiscal impact, in terms of human resource efficiency, capital expenditures, and return on investment
- Strategic/tactical considerations that may result in a competitive advantage for your institution
- Potential alternative solutions, and why they were ruled out

## Design Considerations

Unfortunately, many existing pharmacies are "land locked" and remodeling must occur within a fixed physical plant space. This makes a retrofit more difficult and often eliminates the consideration of a soft wall cleanroom. Because soft wall cleanrooms can be erected in a warehouse space and can be built quickly, they have advantages in certain settings. On the other hand, they can present some challenges in terms of securing the required air changes and pressure gradients. Soft wall cleanrooms can result in a desirable compounding environment when careful attention is paid to detail in the planning and engineering processes. Special consideration must be given to the cleaning processes. Cleaning may be more difficult as the soft walls move, and it is challenging to maintain even mop contact with the walls to ensure adequate cleaning. Be sure to consider the installation of flooring, since typical warehouse floors are porous and do not meet USP requirements. To achieve a desirable compounding environment with soft wall cleanrooms, modifications may be in order. For example, the sidewalls may need to be secured to the floor and additional air returns may be required to achieve appropriate airflows and the desired environment.

## Walls

Photo courtesy of Clean Air Technology, Inc.

*Windows are helpful in allowing personnel to see into the cleanroom from outside.*

Modular, hard wall cleanrooms are constructed offsite to fit the exact dimensions at the site. Walls should be constructed of epoxy-coated gypsum board or interlocking panels made of cleanroom compatible materials, such as fiberglass-reinforced plastic (FRP) or PVC laminate panels. The wall's junction with the floor needs to be coved and sealed. In general, it is best to avoid flat horizontal surfaces, such as sills, exposed piping or conduits, large door jams, or window frames, as they can collect dust. The integration of cabinets into the cleanroom should be avoided and it is best to use carts, preferably made of cleanroom-grade stainless steel. Restock the carts daily with essential supplies only.

## Windows and Doors

The value of windows has been the topic of much discussion. It can be very helpful to see into the cleanroom from the outside, making windows worth the extra dollars per square foot. Doors can also increase the viewable area and oftentimes, full-length window doors are only slightly more expensive than windowless doors. Doors should have gasketed, anodized

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aluminum frames with flush-mounted jams and sills. Particular attention needs to be paid to the upper margin of the door during cleaning. Almost all doors will have an indented section on the top frame where dirt can accumulate. You should consider adding aluminum bars, bent in an inverted U shape, to that space to facilitate cleaning.

## Ceilings and Lighting

Ceilings should be made of cleanroom-grade ceiling tiles or epoxy-coated gypsum board sealed with room temperature vulcanizing (RTV) silicone to an anodized aluminum T bar grid. Each individual tile should be caulked in place to prevent the tile from moving during ceiling cleaning. Instead of caulking, special clips can be installed, but they often break and can make the removal of ceiling tiles difficult. Some vendors may suggest vinyl-coated sheet rock for the ceiling tiles. This material is extremely heavy and, therefore, generally does not require caulking. However, it requires a heavier-grade ceiling support grid, which is more expensive.

I prefer the use of cleanroom-grade ceiling tiles that have been caulked in place. In the event that a ceiling tile needs to be removed for repair or access to equipment above the ceiling, it is very easy to slit the caulking, remove the tile, replace it, and re-caulk. Silicone caulking needs to occur around each tile, as well as around the junction of the ceiling to the walls.

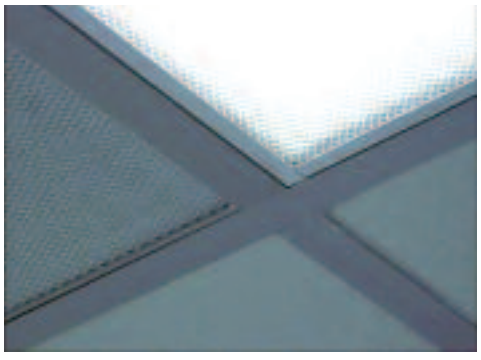
*Photo courtesy of Solunet, LLC*

Lighting should be flush, integrated with an anodized aluminum T-bar grid, and sealed with RTV silicone (see picture at left). Light bulbs must be easy to change from within the room. The lens or cover of the light should be acrylic with a baked enamel finish. It is very important to provide a high degree of lighting to aid in the accuracy of work done within the cleanroom. In some cases, integration of a light and HEPA filter might be required to obtain adequate lighting and HEPA coverage. Consideration should also be given to emergency lighting and sprinkler heads, depending on local building requirements.

## Floors

Floors should be made of wide vinyl sheeting with a minimum of 4-inch coving up the wall. Joints or seams in the flooring should be heat sealed, so that no gaps or crevices exist to harbor microorganisms. Ideally, the molding at the top of the cove should be flat and permanently mounted to the wall to facilitate cleaning. During planning, designate the exact location of the anteroom line of demarcation, and select vinyl sheeting of a different color for the anteroom than that of the main cleanroom. Ask the flooring contractor to integrate the line of demarcation during the installation. This will eliminate the need to use cleanroom tape, which requires frequent replacement, on the flooring. Before installation, explain the need to prevent crevices and gaps to your flooring vendor. Attention needs to be paid to corners, where the coving needs to be neatly slit and fit together. Before releasing your flooring contractor, you or another member of your team should personally examine every inch of the floor perimeter and silicone any edges that remain after cutting.


*Photos this page courtesy of SoluNet LLC.*

## Pass-Throughs

Optimally, a pass-through—a separate entrance into the controlled environment for components and supplies—should be considered to decrease the likelihood of airborne contamination and to improve efficiency. Pass-throughs should have physical dimensions that suit your needs. To determine the size necessary for your pass-throughs, consider the following:

- The number of workstations in the cleanroom
- The size of batches prepared
- The volume and size of your final CSPs
- The size and volume of raw components

Pass-throughs can range in size from a 24-by-24-inch wall insert to a size large enough to accommodate a 36-by-28-inch stainless steel cart (see picture above). All pass-throughs should be gasket-sealed, but options include latches, mechanical interlocks, laminar flow filtration, and materials such as stainless steel, acrylic enamel, anodized aluminum, and epoxy-painted.

## Gauges

Though the pressure differentials required by USP Chapter <797> may change, some degree of positive pressure will be required for a non-hazardous compounding cleanroom. If compounding agents have been designated as hazardous by NIOSH, a negative pressure room is required. In either case, installation of a magnehelic gauge or gauges is recommended, though not currently required. It is important to be able to measure, monitor, and document the critical pressure differentials on a daily basis, and the gauges aid in that task. If only one gauge is to be installed, it is recommended that the gauge measure the pressure from the cleanroom to the adjacent workspaces. It is also potentially useful to use one gauge to measure the pressure from the cleanroom to anteroom, and another to measure the anteroom pressure to the adjacent non-classed pharmacy preparation area. The total of the two pressures can also be documented. At a minimum, however, there should be a gauge for each cleanroom in the pharmacy complex.

## Sinks, Hand Dryers, Knee Valves, and More

All sink fixtures should be stainless steel to facilitate cleaning and stand up to the rigors of regular use. It is important to make certain that the size of the sink selected will accommodate the buckets you may use for clean-

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**Look for the second part of this article in our next issue!**

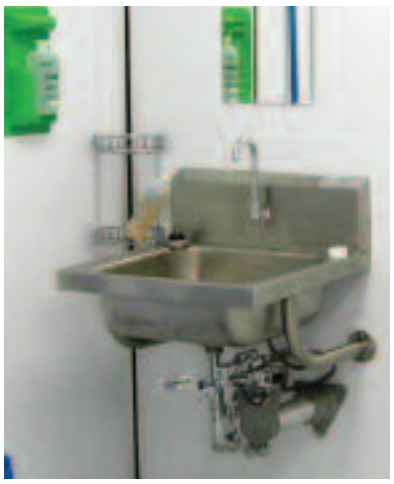

Photo courtesy of SoluNet LLC.

*CLEANROOM (Continued from page 10)*

ing. It is also important to work with the plumbing contractor and cleanroom vendor to design a shroud or cover that can fit over the water controls and pipes, because they can be difficult and time-consuming to clean. Ideally, the shroud would be removable and made of the same materials as the cleanroom walls. A larger sink can be heavy, so work with the vendor to make sure the sink is properly mounted on a beam or that additional support is offered. Mount a mirror (flat with no ornamental molding) to the anteroom wall, so that personnel can use it during gowning to make certain that their hair is completely covered by their bouffant caps. Remember to mount an eye wash station near the sink. Ideally this unit would be integrated with the plumbing, but a free-standing unit can also be effective (see picture above).

You should also decide whether to invest in hands-free water controls, such as foot pedals or knee valves. Though experience with knee valves (a relatively inexpensive mechanism) has been overwhelmingly positive, some believe they may increase the risk of injury, especially in very small anterooms. After washing one's hands and drying them with lint-free wipes, it is perfectly acceptable to turn off water spigots with a lint-free towel.

Hand driers are not required by USP <797>, though they have become a popular item. I do not favor hand dryers for the following reasons:

- The cost of purchase, installation, and repair
- Many dryers take too long to completely dry hands, and as a result, staff will either don gloves before their hands are dry or use lint-free wipes to finish drying their hands, thereby increasing the costs associated with hand dryers.

## Furniture

Furniture should be made of cleanroom-grade stainless steel. Hard plastic furniture is permissible, but it is more difficult to clean and its appearance will deteriorate significantly over time. With that in mind, all furniture should be constructed of smooth, impervious materials that can be efficiently and effectively cleaned. Carts, shelving, and stools should also be on casters for easy moving during cleanroom cleaning procedures. The cost of stainless-steel furniture will account for a significant portion of a cleanroom budget ($3,000 to upwards of $18,000), a cost that is often overlooked during planning and budgeting. In some applications, the use of stainless-steel carts with wire shelving is preferred, as flat-surface shelving can be more disruptive to unidirectional airflow.

## Power Supply

Even if you do not currently use automated compounders or other devices that interface with software, the installation of CAT 5 wiring and a GCFI outlet at each workstation is strongly recommended. You are likely to employ this automation in the future, and retrofitting cleanrooms can be overwhelming and costly. Consider your emergency/disaster plan, and if your pharmacy requires a back-up generator, speak with hospital personnel to ascertain if their generator/s have unused capacity. Work with your cleanroom/HVAC engineer to determine generator requirements for your cleanroom. If you use automated compounders, consider wiring your lights, compounders, and computers to a central UPS (uninterruptible power supply). If that is impossible, it is strongly suggested that each computer and compounder be on their own smaller UPS that can be purchased at local computer accessories stores. Power surges or brown outs can cause loss of data and products already pumped into the final container. Depending on the equipment, individual UPS units can provide power for the compounder/computer for 10 to 50 minutes.

Keep in mind that computers and other devices need to be cleaned according to their location, therefore keep cords and equipment off the floor, which must be cleaned daily. Plastic covers can be used for keyboards, but they must be cleaned at least daily as well. Flexible, waterproof keyboards are available, but may not be compatible with all compounding equipment. Mice must also be cleaned daily. (Most optical mice will not work on stainless steel.) It is also recommended that you install a local area network so that printers—voluminous particle generators that they are—can be located in the non-classed areas. Labels can be printed in the prep area and staged with batch components to be brought into the cleanroom.

When planning for the size of your cleanroom and/or the number of hoods you will have in the room, remember that hoods cannot block air returns and they must be positioned at least 4 to 6 inches from the wall to facilitate cleaning. It is recommended that the walls and other vertical surfaces, such as the sides and back of hoods, be cleaned weekly. As such, this equipment needs to be positioned for feasible cleaning.

## Summary

There are many factors to consider and choices to be made in the design of a compounding complex, but careful planning can minimize the angst associated with these projects. The development of compounding environments that not only meet regulations, but also function well when in use, requires significant forethought. It is critical that pharmacists understand their current and future needs relative to the type of CSPs they are or will be compounding. From that understanding, your facility design criteria can be developed and act as a guide during planning meetings and serve to both communicate with vendors and hold them accountable to your desired results. Knowledge is power, and only an educated customer can build a cleanroom that both complies with USP Chapter <797> and meets your pharmacy's workflow-efficiency needs. PP&P

## Additional reading:


1 Kastango, Eric S and DeMarco, S. Cleanroom Project Management Considerations: An experienced based perspective. *IJPC*. Volume 5, Number 3; May/June 2001; 221-225.

2 Wagner, James T. and Kastango, Eric S. Understanding Pharmacy Cleanroom Design Requirements. *PP&P*. Volume 2, Number 1; February 2005; 16-19.



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