



Cleaning Your Sterile Compounding Areas: **Policies, Product Choices, and Personnel Competency**



Photo courtesy of ITW Texwipe

AS THE PHARMACY COMMUNITY WAITS FOR THE IMMINENT RELEASE OF updates to USP <797>, many are speculating how these changes will impact compounding practice, while others have chosen to ignore the discussion altogether, justifying their position by claiming there is a lack of sufficient evidence-based data to support the notion that changes to cleanrooms and compounding practices are needed at all. However, the fact remains that USP <797> represents a best practice for the compounding of sterile preparations. Even in the absence of specific legal requirements, pharmacists should assess the chapter's applicability to their practice and change their procedures as they deem necessary. This exercise can protect both the pharmacist and the patient, and can assist pharmacists in maintaining compliance with current standards.

I prefer to learn from the lessons of history and not repeat previous disasters. In the late 19th century, Joseph Lister and other luminaries of the age suggested that the presence of bacteria could cause infection. The scientific basis for cleanrooms was developed out of the effort to minimize or eliminate the presence of bacteria, with the goal of reducing the incidence of infections in hospitals. Intense focus was placed on hospital operating rooms to achieve this goal. During this time, the discovery was made that the incidence of airborne infections could be greatly reduced by providing proper ventilation of critical areas.

During the '60s, a team of scientists developed the concept of the modern cleanroom. These advances in technology brought with them a need to quan-

tify the level of performance of these controls, and in 1963, the first national standard for air cleanliness was developed, Federal Standard 209A. In 1992, following several revisions to the federal standard, the International Organization for Standardization (ISO) developed an international standard, and in 2001 the United States Government retired FS 209E and replaced it with ISO-14664-1.¹

Why Is Cleaning Necessary?

So why is there all this confusion over technology and standards that were developed and have been proven over the last half century? The answer lies within the fact that "cleanrooms" really do not clean anything. Cleanrooms are controlled environments in which critical operating standards can be maintained, predominantly by the compounding complex's primary and secondary engineering controls. However, there is no substitute for the vigilance of compounding personnel in keeping these critical environments clean. Even if a cleanroom's engineering controls are sufficient and functioning properly, and even if strict garbing, hand washing, and other gowning procedures are in place, consistent and effective cleaning and disinfection procedures are still needed to continually decrease bioburden (i.e., particles) within the facility. Bioburden serves as a transport medium for viable contamination, so care must be exercised to reduce the sources of any particulate matter.²

Product Selection

Careful consideration must be given to the cleaning products and chemical agents employed in your compounding areas. You must take the time to think through all the parts and pieces that make up your overall cleaning program to ensure the program is effective, practical for every day activities, and does not degrade the ISO Class 7 or 8 air quality.

There are a myriad of choices in cleaning agents and their expense and actions vary greatly. Though isopropyl alcohol is widely used to clean ISO Class 5 compounding surfaces, 3% hydrogen peroxide and 2% sodium hypochlorite (bleach) are also effective as sanitizing agents.^{2,3} Your protocol should include a rotation of cleaning agents to prevent development of resistant microflora.⁴ Whatever agent is chosen, it is also of paramount importance to follow the manufacturer's recommendations with respect to the storage, handling, and dilution of the product. USP <1072> (Disinfectants and Antiseptics) is a good resource in this area.

USP <1072> includes information on both hard surface and skin sanitization techniques, both of which are important to maintaining microbial control of pharmaceutical manufacturing areas. The document states, "The cleaning and sanitization program should achieve specified cleanliness standards, control microbial contamination of products, and be designed to prevent the

chemical contamination of pharmaceutical ingredients, product-contact surfaces and/or equipment, packaging materials, and ultimately the drug products." These issues are relevant not only for aseptic areas and products, but also for non-sterile forms of product dosage.⁵

Beyond the agents used, the cleaning equipment employed must also be carefully considered. Buckets, mop handles, and mop heads should be chosen with care. Cleaning equipment should be selected for its ergonomics, durability, and construction. Sometimes the equipment with the lowest acquisition price has a considerably shorter useful life than more expensive, yet more durable products. In other words, low-priced items may end up costing more in the long run. For example, conventional cellulose sponge mop heads are relatively inexpensive, but begin to breakdown within one week and should be changed as soon as they show signs of wear, and conventional mop handles are not designed for the rigors of the cleanroom environment and rarely last more than one month. Additionally, inexpensive mop buckets designed for household systems may become too heavy when filled or may be too large to fit in your pharmacy's sink. Therefore, they are frequently inappropriate for cleanroom cleaning applications.

Fortunately, there is a better solution. Try a stainless steel mop system, with interchangeable handles and swivel mop heads that use disposable pads or covers specifically designed for ISO Class 5 areas. Although the initial investment will be higher, the annual savings will be realized in the less frequent changing of the handles. Furthermore, this efficient system will save staff time and can improve staff morale and acceptance of your cleaning protocol.

Likewise, the use of larger lint-free wipes, for example a 12-by-12-inch wipe, may carry a higher acquisition cost than smaller wipes, such as a 9-by-9-inch wipe, but may reduce the number of wipes used during a cleaning cycle, and could, in fact, save money. Furthermore, the

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Cleaning

FIGURE 1. CLEANING COMPETENCY/SAMPLE FORM

Employee: _____ Facility: _____ Date: _____

Pass: Full compliance: Meets *all* provisions of standard or policy and procedures

Fail: Non compliance: Fails to meet *all* the provisions of the standard or does not follow policy and procedures.

| OPERATIONAL: | Pass | Fail | N/A | COMMENTS |
|--|------|------|-----|----------|
| Preparation of Cleaning Solution | | | | |
| For Class 100 areas: 40 mL Bleach into 2 L Sterile Water for Irrigation making a 2% bleach solution. Label container with mix date and seven days expiration. | | | | |
| Label container with Corrosive warning label. | | | | |
| General room cleaning: 20 mL Bleach for each 1 L of tap water used. Use appropriately labeled bucket for the type of surface to be cleaned (floor, wall, production bins, etc.) | | | | |
| Document cleaning solution preparation in your facility's log | | | | |
| Gowning procedures will be followed when cleaning the clean-room suite. | | | | |
| Daily: | | | | |
| Clean all Class 100 clean benches prior to production in the following order: back wall, IV bar, compounders, and clean bench surface. Use a lint-free wipe soaked with a 2% bleach solution made with Sterile Water for Irrigation. Allow to dry. | | | | |
| At end of day: Remove all compounding components and clean all Class 100 areas as stated above. Clean floors, using a mop labeled "floors". Starting at the wall opposite the room entry door, clean floor surface in even strokes toward the operator. Move carts as needed to clean entire floor surface. | | | | |
| Clean cart surfaces as needed with wipe soaked with 2% bleach from squeeze bottle or sprayer. | | | | |
| Empty trash bins and re-line. | | | | |
| Anteroom: Clean sink and surfaces, and clean floor with 2% bleach solution. | | | | |
| Weekly: | | | | |
| On the designated weekly day, weekly cleaning is performed. APPROVED CLEANER is to be used once per week for cleaning of all surfaces. | | | | |
| Weekly cleaning includes all daily cleaning as outlined above and, in addition, all totes, carts, and wall surfaces are cleaned. | | | | |
| Totes: Remove contents. Using a 2% bleach-soaked lint-free wipe, clean the inside surfaces of the tote and then the entire exterior surfaces of the tote. Allow to dry. Replace contents of tote. Use new wipe as needed. | | | | |
| Carts: Using a 2% bleach-soaked lint-free wipe, clean all carts starting with the top shelf and top of post, working down to wheels. Clean the under side of shelves in a similar manner. Use a new wipe for each cart. | | | | |
| Clean chairs, the interior and exterior of trash bins, and production bins. | | | | |
| Monthly: | | | | |
| Perform monthly cleaning the first week of the month, on the same day as weekly cleaning. | | | | |
| Monthly cleaning includes all weekly and daily cleaning as above, and in addition, the cleanroom ceiling is cleaned with a 2% bleach solution and a roll-a-matic mop. Start with interior of Class 100 clean bench. Clean ceiling then clean bench interior walls and then clean bench surfaces. Once Class 100 area is clean, perform cleaning of compounding room ceiling, then the walls and finish with floor. Use appropriate labeled mops. | | | | |
| Monthly cleaning includes interior and exterior of refrigerators and incubators, as well as ceilings and walls of anteroom. | | | | |
| Document all cleaning in facility's log. | | | | |
| Three-Time Cleaning: | | | | |
| Three-time cleaning is required when a cleanroom is initially built, prior to any production in room. | | | | |
| Three-time cleaning is required after every room certification, after any construction within the cleanroom prior to production, or as required when the operational integrity of the classified room has been compromised. | | | | |
| A three-time cleaning involves three consecutive monthly cleanings with appropriate drying time between each cleaning. | | | | |
| The first and second cleaning use a phenolic disinfectant compound (i.e. the facility's disinfectant of choice) and the cleaning agent. The third cleaning uses a 2% bleach solution. | | | | |
| Document three-time cleaning in facility's log. | | | | |

Figure courtesy of Certified Consultant Pharmacists, Inc.

If a "Fail" is achieved in any standard, review standard and note under the comment section. Repeat competency assessment until all standards are passed.

Pharmacy Operations Manager Signature _____ Date _____

Employee Signature _____ Date _____

This form is also available for download at www.pppmag.com

use of pre-moistened wipes may seem like an extravagance, but can promote labor savings if their use assists the staff in effectively cleaning the rooms in less time. Additionally, some of these pre-moistened wipes are available with dispensers that can be operated with one hand, which may encourage better technique among your personnel.

The Cleaning Process

To prevent cross contamination cleaning equipment should be clearly labeled with its designated area, and should not be used interchangeably in multiple areas. For example, equipment used to clean walls and ceilings should not be used to clean floors, nor should these mops be taken outside the pharmacy area. In general, you should employ a "cleanest to the dirtiest" methodology, working from the ISO Class 6 or 7 area to the ISO Class 8 area. Likewise, cleaning should generally be performed from "top to bottom". For example, the cleaning order for a monthly clean would be: ceilings; walls, windows, and horizontal surfaces; workbench shields; ISO Class 5 surfaces; workbench or hood legs; and finally the floor.

Observation and Competency Assessment

The cleaning and disinfecting practices described within <797> relate to direct and contiguous compounding areas (DCCAs), including the ISO Class 5 compounding areas, as well as buffer rooms, anterooms, and ante areas. It is stipulated within the current chapter that trained compounding personnel are responsible for developing and practicing written procedures for cleaning and disinfecting DCCAs. Mopping may be performed by trained and supervised custodial personnel using agents approved in your pharmacy's written procedures but whether compounding personnel perform the cleaning themselves or an external cleaning service is used, it is ultimately the compounding personnel's responsibility to assure that your own written policies are being followed.³

Regardless of who performs the cleaning functions they must be carefully trained, directly from the organization's written procedures, as well as educated in proper garbing and hand washing. There are many factors to consider when developing an overall cleaning and disinfecting program for your compound-

|  | | WHERE TO FIND: Controlled Environment Cleaning Products | |
|---|------------------|--|------------------|
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ing complex, and the hospital's operating-room director is an excellent resource as you develop your formalized cleaning and disinfecting protocols.

In the final analysis, your largest expense related to cleaning and disinfecting is labor. The better training you provide and the more comfortable personnel is with what they are doing and why they are doing it, the better results you can expect.

Once you have selected the proper tools for cleaning, routine observation of the individuals during cleaning procedures is recommended. A formalized cleaning competency checklist can be helpful for both training and periodic inspection purposes, as it outlines your basic cleaning protocols and can guide your staff through all of the essential steps to the efficient completion of these critical tasks. This checklist serves as a data collection tool for further staff training and will assist in making the entire process more efficient, while helping the staff understand all the implications of these tasks. If certain steps are continually performed outside of your policies and procedures, these processes will likely require repeated in-depth training. (See Figure 1 for a sample cleaning competency form; you can also download the form at www.pppmag.com.)

Conclusion

There are many factors to consider when designing a USP <797>-compliant cleaning and disinfecting program for your compounding operation. The proper cleaning products must be selected, clear policy and procedures must be established, and training materials and competency documents have to mirror your standing policy. Finally, all these elements must come together so that the staff involved in these daily activities can perform these tasks efficiently and effectively to assure the safe operation of your compounding operations. Even if financial resources are not yet available to upgrade your existing environmental engineering controls or install new ones, pharmacies can comply with USP <797>'s gowning, hand washing, and cleaning requirements right now for a relatively minimal expense. ■



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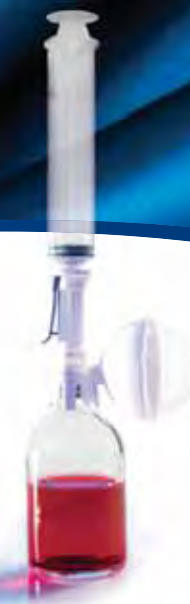
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