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By Lou Diorio, RPh

# Best Practices and Budgeting for **Cleanroom Wipes and Cleaning Agents**

Like a comprehensive blueprint, USP <797>, when read in its entirety, provides a science-based roadmap to fulfilling its primary objective – preventing patient harm. When implementing the standards set forth in the chapter, deciding where to begin can be the most daunting step. It may be preferable to break a task as complex as the proper preparation of CSPs into smaller, easier-to-digest portions. For instance, perhaps the most basic aspect of a cleanroom's daily life cycle is its cleaning and upkeep. Fortunately, the recently revised USP <797> contains a robust section on "Cleaning and Disinfecting the Compounding Area," providing a basis upon which to build your cleanroom cleaning protocols. <797> cites environmental contact as a major source of microbial contamination, and cautions that "scrupulous attention"[1] to cleaning and disinfection of compounding areas is required to minimize it. The chapter also states that all cleaning and disinfecting practices shall be included in written policies and procedures to be followed by all compounding personnel.

## How Often Should You Clean?

Surfaces in the direct compounding areas (DCAs) of your cleanroom require more frequent disinfecting than surfaces such as walls and ceilings. A DCA is defined as an area within an ISO Class 5 engineering control where critical sites (such as injection ports, needle hubs, and opened ampoules) are exposed to unidirectional HEPA-filtered air. USP <797> outlines the following minimum cleaning intervals for your compounding areas:

| Critical Site | Minimum Frequency |
|---|---|
| **ISO Class 5 primary engineering controls** | •At the beginning of each shift<br>•Before each batch<br>•Not longer than 30 minutes after the previous surface disinfection (during ongoing compounding activities)<br>•After spills<br>•When surface contamination is known or suspected |
| **Counters and work surfaces** | Daily |
| **Floors** | Daily |
| **Walls** | Monthly |
| **Ceilings** | Monthly |
| **Storage shelves** | Monthly |

## Wiping Technique

Critical cleaning procedures differ greatly from the casual, cursory wiping approach one takes at home to clean kitchen counters.[2] In fact, neither the wiping material nor the wiping action used at home is appropriate for the critical cleaning required in compounding areas. Proper wiping action puts the fabric in intimate contact with the surface, allowing the application of strong forces for the removal of contaminants. Proper wiping has a long and successful history of removing contaminants from cleanroom surfaces. However, to be successful, the wiper must be used properly. For a primer on best wiping practices, see Figure 1.

For general wiping, use the wipers identified in your cleaning/disinfecting protocol. When using pre-wetted products, you may fold the wiper in quarters, as prescribed in Figure 1 and begin wiping. When using dry wipers and a liquid cleaning or sanitizing agent, be sure that the wipe is sufficiently dampened with an approved cleaning or disinfecting agent. The cleaning and disinfecting agents must be approved for cleanroom use, regardless of organizational or institutional policies.

## Selecting the Proper Wiper Material

Your written cleanroom cleaning policies should include guidance for the selection of proper wiper materials. Although <797> mentions lint-free wipes exactly eight times, the chapter never outlines the exact composition necessary in cleanroom wipers. With selection left to the compounder, and multiple product choices available from a number of suppliers, purchasing an appropriate wiper for cleanroom applications can be a confusing task.

A wide variety of fabrics are fashioned into wipers and mops for "cleanroom applications." These materials include cotton, rayon, and cellulosics, and synthetic materials such as polyester, nylon, polypropylene, or foams, as well as blends of these materials. Of these myriad of choices, only polyester knit fabrics have the cleanliness, low particle and fiber counts, low endotoxin levels, low extractable residues, durability, and chemical compatibility needed for the cleaning and disinfecting of DCAs. Simply stated, when used properly, polyester knit wipes and mop covers will not contaminate critical surfaces and represent the best choice among "non-linting" or "non-shedding" materials for cleanroom cleaning and disinfecting applications.

## Dry vs. Pre-Saturated Wipes

Many facilities wrestle with the choice between using pre-saturated wipes versus obtaining dry wipes of the same composition and applying a disinfecting agent immediately prior to their use. Likewise, pharmacies must determine if a spray bottle is the best or most economical way to apply liquid disinfecting agents to DCAs.

Convenience is the key to answering these questions. If compounding personnel can conveniently access wipers and disinfecting agents, it is not unreasonable to expect that the necessary cleaning will be done, assuming the staff has been properly trained, tested for competency, and is re-trained as needed. Further, the availability of wipers near the work area will visually reinforce the need to maintain the cleanliness of the DCA, as well as compounding personnel hand hygiene. Your staff may prefer pre-saturated wipes, because they eliminate the need for spray bottle application of disinfecting solution and can speed workflow. As the popularity of pre-wetted wipers increases, more packaging options, such as "pop-up" and one-handed dispensers, are becoming available. Should your facility decide to use pre-wetted wipers for the majority of its cleaning tasks, dry wipers must always be available to handle the occasional spill of liquids.

# Cleaning the Cleanroom

## Figure 1. Cleanroom Wiping Guide

1. Follow relevant site protocol (procedures for safety, contamination, etc.) and wear cleanroom gloves.
2. Fold wiper in mid-air into quarter folds (Fig. 1A–1C). This will produce several clean surface areas and allow better contact with the surface to be wiped.
3. When wiping, hold the wiper so that the folded edge is toward the area to be wiped. Hold the unfolded edges in your hand. Group the unfolded edges between thumb and forefinger.
4. Use either a pre-wetted wiper or a dry wiper moistened with an appropriate cleaning agent.
5. Wipe in one direction, overlapping wiped area by 10% to 25%.
6. Wipe from cleanest to least clean regions of the surface being wiped. Wipe systematically, for example, from top to bottom, far to near. (Fig. 2)
7. Keep track of which surfaces have been cleaned and which wiper areas are unused.
8. Always use the cleanest surfaces of the wiper. If re-wiping use a clean portion of the wiper, not the used wiper area.
9. Dispose of wipers according to site procedures.

**Wiping Wet Spills**

1. Identify the spilled liquid. Follow the Material Safety Data Sheet (MSDS).
2. Choose wiper and gloves that will not be degraded by the liquid.
3. For hazardous spills, wear two pairs of gloves and try to keep the gloves dry. Wear any other necessary protective gear.
4. Use dry wipers to wipe spills up immediately. Then clean the affected surfaces by following steps 1-9 above.
5. Dispose of wipers according to site procedures.

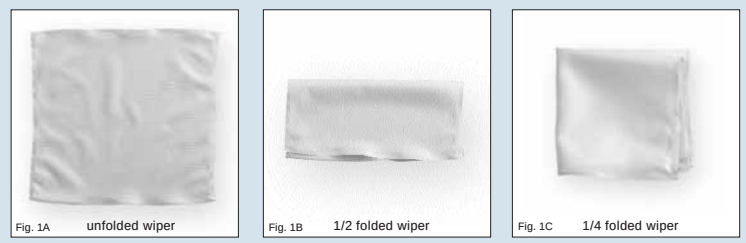

Fig. 1A unfolded wiper | Fig. 1B 1/2 folded wiper | Fig. 1C 1/4 folded wiper

Fig. 2

Information and photos courtesy of ITW Texwipe

Aside from user convenience, you must also consider the cost of the type of wipers you select. In general, pre-wetted products have a higher acquisition cost than dry wipers. Dry wipes are available for around $0.20 to $0.25 per wipe, depending upon the size and material used, while pre-wetted varieties cost $0.20 to $0.55 per wipe, depending upon the size and composition of the wipe, as well as the container or dispenser. When conducting a cost analysis of dry versus pre-wetted wipers, you must include the cost of disinfecting or cleaning agents in your calculations. However, the good news is the availability of these items from multiple suppliers, and the recent trends by group purchasing organizations (GPOs) to solicit bids for these items, have led to some downward movement in pricing.

### Cleaning/Disinfecting Agents

USP <797> now requires the use of sterile 70% IPA for the disinfection of sterile gloves and critical sites, and specifies it as a suitable disinfecting agent. There has been some resistance to this change, as sterile 70% IPA is more expensive than non-sterile 70% IPA. However, the USP's Sterile Compounding Expert Committee did not make this change lightly, adopting "the use of sterile 70% IPA...after considering published data and recommendations from multiple commenters [sic] including the advisory panel formed to review the section." It is the committee's position that the use of sterile 70% IPA can reduce the risk of bioburden in compounding areas.[3]

Of course sterile 70% IPA cannot be the sole agent used. The chapter recommends several agents for use in your critical environments in Appendix II. The selection and use of cleaners and disinfecting agents is influenced by many properties. Microbicidal activity, inactivation by organic matter, residue, and active shelf life are among the paramount concerns when selecting these products for cleanroom use. Many compounders have embraced the use of "one-step" disinfectants; these products are formulated to be effective in the removal of light soiling, without the need for a pre-cleaning step. However, for heavy soiling, a cleaning step prior to disinfection is recommended.

The requirement to use sterile 70% IPA as a disinfecting agent has led pharmacies to seek the most economical method for sourcing these products. Pharmacies can employ either dry wipers and spray bottles of sterile 70% IPA or wipers pre-wetted with sterile 70% IPA – or a combination of both. Conversion to sterile 70% IPA is not without its budgetary woes: Most facilities can currently purchase 480 mL of non-sterile 70% isopropyl alcohol for $1.50 to $2.50, while the acquisition cost for the same amount of sterile 70% IPA is currently $5.02 to $9.95, leading to an increase in disinfection costs for the average cleanroom operator.

### Ensuring the Effectiveness of Your Wiping Program

How can you determine if your staff is indeed using the wipers and disinfecting agents properly? Auditing the cleanroom on a regular basis will provide information on cleaning frequency and the effectiveness of your program. Look for used wipes in the trash. In addition, the appearance of surfaces to the naked eye and under high illumination at oblique angles can uncover inconsistencies in wiping. Your environmental surface sampling results also serve as a good barometer of your wiping success.

### Conclusion

The task of the modern director of pharmacy is to balance the convenience of pre-made items with the cost-effectiveness of separate components. It is impor-

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**WHERE TO FIND IT**

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| Vendor | Reader Service Number | Lint-Free Wipers | Sterile 70% IPA |
|---|---|---|---|
| Acute Care Pharmaceuticals | 31 | X | X |
| Anticon/Milliken & Company | 32 | X | |
| Attentus Medical Sales, Inc. | 33 | X | X |
| Berkshire Corporation | 34 | X | |
| Decon Laboratories, Inc. | 35 | | X |
| ITW Texwipe | 36 | X | X |
| Kimberly-Clark Professional | 37 | | |
| Liberty Industries, Inc. | 38 | X | X |
| Lymtech Scientific | 47 | | X |
| Micronova Manufacturing, Inc. | 48 | X | |
| Miller Products Company | 50 | X | X |
| NuAire/Scientific Visions, Inc. | 51 | X | X |
| Spectrum Pharmacy Products | 52 | X | |
| Technowipe, Inc. | 53 | X | |
| Valutek | 54 | X | |

tant to remember that the time your staff spends cleaning your compounding areas has an associated cost of labor – beyond the price tags on your wipers and disinfecting agents. As a director of pharmacy, you should examine all of the work practices in your compounding operations to identify your facility's "best practices" and ensure all of your staff members are comfortable with the products being used to maintain the integrity of the compounding environment.

Compliance with USP <797> involves upfront and ongoing costs.[4] The cost of proper cleaning represents a notable portion of the budget you must allot to the maintenance of your cleanroom and DCAs. However, the decrease in bioburden derived from the proper selection of these simple but effective products may assist compounding personnel in preparing safer CSPs and prolong the overall useful life of the cleanroom complex itself. ■

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