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Case Study

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Establishing a Formal Cleanroom Cleaning Strategy



Photos courtesy of Professional Disposables, Inc.

MAINTAINING THE INTEGRITY OF THE CLEANROOM ENVIRONMENT POSES significant and continuous challenges, partially due to the two main sources of particulate contamination that can compromise the air quality: personnel and products used for compounding. To maintain the cleanroom as outlined in USP Chapter <797>, sterile compounding managers should develop set procedures to minimize entry of particulate matter. These procedures must include the establishment of a formal cleaning schedule.

A Formalized Cleaning Strategy

A formalized cleaning plan and schedule for sterile compounding areas is essential to continually minimize air particulate contaminations. All areas within the anteroom and compounding area need to be addressed and can be placed on a daily, weekly, or monthly cleaning schedule, based upon the room and surface area.

Nebraska Methodist Hospital (NMH) is a 440-licensed bed, not-for-profit facility located in Omaha, Nebraska. In 2006, the department of pharmacy services compounded 325,029 low- and medium-risk sterile products, in addition to 2,107 sterile hazardous drugs. NMH has a formal sterile compounding area with a 500-square-foot anteroom, a 400-square-foot ISO Class 7 cleanroom, and another 120-square-foot ISO Class 7 cleanroom designated for hazardous drug compounding. The following is NMH's cleaning schedule, which is managed by pharmacy personnel and carried out, in part, by the surgical services housekeeping team:

Surface	Clean Room	Anteroom	Hazardous Drug Room
Counter tops	Daily	Daily	Daily
Carts	Weekly	NA	NA
Shelving	Weekly	Weekly	Weekly
Top of laminar airflow hood	Monthly	Monthly	Monthly
Electronic devices	Monthly	Monthly	Monthly
Storage bins	Weekly	Monthly	Monthly
Floors	Daily	Daily	Daily

Our pharmacy staff documents the completion of each task on a form to be monitored by the sterile compounding manager. A separate form is used for each area. At NMH, three certified pharmacy technicians are assigned to clean one room each. To minimize cleaning time, anteroom inventory is limited to a four-day supply and wire shelves are utilized. The cleanroom can take two hours to clean, and the anteroom takes one to two hours to clean in two separate sessions. We divided our anteroom into two separate areas for cleaning to minimize the disruption to workflow. The hazardous drug room has minimal inventory and takes about an hour to clean. During the cleaning process outdates are also checked. The floors are cleaned by the housekeeping staff each evening.

All of our cleanroom cleansers have been approved by NMH's epidemiology department to ensure that they meet the requirements for high-level disinfection.

Counter tops, shelving, and storage bin surfaces are cleaned using PDI Super Sani-Cloth germicidal disposable wipes. We cleanse the carts used in the transfer of products and the outer surface areas of our laminar flow hoods with a high level disinfectant, STERIS LpH-Se. Personnel don gloves to protect themselves from exposure to these agents. It is important to note that these disinfectants destroy all microorganisms with the exception of highly concentrated bacterial spores. We disinfect our anteroom sinks daily with LpH-Se. Outside of established cleaning times, NMH's housekeeping personnel are not allowed to enter the cleanroom. Pharmacy staff moves all rubbish from the cleanroom to the anteroom twice daily. All sharps are disposed of in red biohazard sharps containers. Hazardous waste is disposed of in yellow or black containers, based upon regulated waste streams. These containers are managed by housekeeping once they are filled and sealed by pharmacy personnel.

Cleaning the Cleanroom

The NMH cleanroom is cleaned by surgical services housekeeping personnel. The vents and floors are cleaned on a daily basis, and on a monthly basis, the room is "term-cleaned," to ensure that a clean environment is created and maintained to the same standard as the NMH surgical suites.

For daily cleaning, the cleanroom floors and vents are cleaned using STERIS Coverage Concentrate made according to manufacturer's specifications. A department-dedicated bucket is used to prevent contamination from other areas of the hospital. Prior to entering the cleanroom, housekeeping personnel don appropriate garb. The vents are first wiped with a clean cloth. Then the floor is cleaned, starting from the farthest corner of the room and proceeding to the entry room door.

For the term cleaning of the cleanroom, pharmacy personnel ensure that compounding of all sterile products is completed for the day. The rooms are then cleaned in the following order:

1. Pharmacy personnel remove all open products.
2. Housekeeping divides the room into three sections, with three surgical services housekeepers cleaning at the same time.
3. All furniture, equipment, and exposed cords are cleaned with Coverage Concentrate, including:
 - a. Wheels and casters of carts
 - b. Clocks, air vents, and grates
4. Ceiling grates and light fixtures are cleaned.
5. The top of the laminar flow hood is cleaned.
6. The ceilings are cleaned.
7. The walls are cleaned.
8. The floor is cleaned.
9. Cleaning starts at the farthest corner of the room and proceeds to the entry room door. After cleaning the room the housekeeping staff documents their activity on a log sheet that is co-signed by the pharmacist.

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significant one-time capital expense (\$3,000-\$10,000), there has been an uproar over the expense of these collection devices, despite their scientifically proven superiority. It would appear that when something is not convenient, is expensive, or takes too much time to perform or supervise, we don't or won't do what's right, despite the science behind the activity.

The Challenges of a One-Size-Fits-All Regulation

It is reported that there are about 800 to 900 high-volume compounding pharmacies with reported sales in excess of \$2 billion annually. These operations should be regulated differently than the average compounding pharmacy. But it begs the question: Is it possible to write a compounding regulation that is applicable to all facilities? There are several factors that make a "one-size-fits-all" regulation tenuous, including the following scenarios:

- Many pharmacists, by choice or necessity, compound patient-specific sterile preparations using bulk non-sterile active pharmaceutical ingredients in order to meet the patient's therapeutic needs when no commercial drugs are available. When does the pharmacy cross the line and become a manufacturer?
- Patients will not be able to access care because the cost of compliance will discourage rural practitioners who only compound a few CSPs per week. At what point does a practitioner have to comply with the regulations?
- Some state boards of pharmacy permit pharmacists to compound non-patient-specific sterile preparations for office use (bulk vials), making some pharmacies seem more like manufacturers, but this flies in the face of federal regulations. Do these pharmacies have to comply with different standards?
- The ongoing tug of war between the FDA, compounding facilities, and state boards of pharmacy over the point at which a compounding pharmacy becomes a manufacturer has spurred the FDA to post on May 31, 2007 a document titled "The Special Risks of Pharmacy Compounding" (available at www.fda.gov/consumer/updates/compounding053107.html).

The practices, processes, and procedures found in the next, soon-to-be-released version of USP Chapter <797> need to be embraced by all pharmacies. And as the revisions to <797> are incorporated into practice, and everyone starts believing that the moving target known as USP Chapter <797> isn't moving any more, the excuses for not complying will go away. It is a robust document with the express purpose of building quality into compounded sterile preparations and ensuring patient safety. Evidence-based science exists for many of the practices that need to be managed, monitored, and measured and many of these are based on best practice; the answer is: Put patient safety first and embrace <797>. This chapter will continue to spark additional research that will, in turn, generate the scientific evidence needed to address the gray areas of sterile compounding and answer the questions surrounding best practices.

The bottom line is that USP Chapter <797> is not going away, and compliance is required. Not all state boards of pharmacy are yet on board with this regulation, but it is my hope that the state boards will rise to the challenge and start enforcing it in order to ensure patient safety and keep the FDA out of the practice of pharmacy. ■



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Self-Validation of Air Quality

Once a cleaning schedule is developed and initiated, an environmental monitoring program must be established to ensure the following processes are being followed according to procedure:

- Gowning and gloving procedures
- HVAC performance
- Cleaning and disinfecting procedures
- Material handling procedures

NMH uses the Graseby In-line Suction System by Andersen to collect air samples as part of our environmental monitoring program. A grid was drafted of the cleanroom to ensure that samples were included from all high-traffic areas and areas of expected contamination. An inhibitive mold agar Petri dish (for molds/fungus) and a blood agar Petri dish (for bacteria) are labeled with the room, location, and date, placed into a biohazard bag and hand delivered to the microbiology department for incubation. The plates are incubated for four days and any growth is cultured and identified.

In addition to self-validation, NMH utilizes CSI Testing Inc. of Plymouth, Minnesota, for semi-annual air testing, laminar flow hood certification, and pressure gradient measurements. Reports are compared and monitored for any trends of increased particulates. If increased particulate levels are observed, the sterile compounding staff evaluates the procedures used in that specific area to identify potential sources of contamination.

Conclusion

By following the cleaning procedures outlined above, NMH is able to maintain a compounding environment that complies with the standards set forth in USP Chapter <797>. Establishing a cleanroom cleaning program can be made easier by breaking things into smaller tasks. Begin by looking at your daily processes. Determine if inventory can be minimized, and reduce traffic into the room. Your department of epidemiology can be very useful in helping you determine the correct cleaners and disinfectants to use in your cleanroom, and your surgical services housekeeping department can help you determine schedules, products, and techniques for cleaning your room. Contact your environmental services department to test your HEPA filters and airflow. After implementing your cleaning program, compare before and after air samples to see if your cleaning methods have improved your air quality. Most of all, involve your employees. Have them read USP Chapter <797> and understand the importance of the changes you are trying to establish. They may bring a fresh perspective to the table and come up with some great ideas. ■

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WHERE TO FIND Controlled Environment Cleaning Products:

Vendor	Reader Service Number	Vendor	Reader Service Number
Acute Care Pharmaceuticals	8	Kimberly-Clark Professional	17
Alconox, Inc.	9	Micronova Manufacturing Inc.	21
Attentus Medical Sales, Inc.	10	Professional Disposables Inc.	42
Berkshire Corporation	12	STERIS Corporation	43
High-Tech Conversions	13	Technowipe Lint-Free Wipes	45
ITW Texwipe	14	Williams Medical Company	46