By Lou Diorio, RPh

Developing a Workflow
to Positively Impact Daily Cleanroom Activities

How much of your daily compounding activities are dictated by the physical layout of the rooms? Are you maximizing your most expensive resource – your employees – within those environments when considering workflow changes and/or improvements to your pharmacy cleanroom procedures?

Blaming the limits of your current physical plant is neither prudent nor wise, and even if your organization has plans to remodel or construct a new cleanroom, these changes can take months. What can the average pharmacy do to be more efficient while the plans are being drawn for a new cleanroom complex?

When harmonized with solid policy and procedure, changes to the pharmacy's daily compounding process can go a long way toward making your pharmacy compliant with prevailing statutes, rules, and regulations, not the least of which is USP General Chapter <797>. Daily workflow, both inside the cleanroom and in the main pharmacy, must be considered to formulate an overall solution to meet your organization's needs. Harmonizing these changes with your current training and orientation program for cleanroom personnel should be done to ensure consistent messaging to the employees, as well as the safety, sterility, and purity of compounded preparations.

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Staffing, Scheduling, and Room Preparation

Carefully examine your staffing from shift to shift and the compounding schedule of items they are expected to produce: Does your production respond to foreseeable peak demands (i.e. clinic times, physician work schedules, lab schedules)? Does your scheduling sufficiently factor in scheduled time off for employees, as well as occasional sick days? Substituting personnel who are not fully acclimated or qualified to the rigors of compounding can be not only less productive for your pharmacy, but can also put you at risk for liability.

Entries and exits to and from the cleanroom are costly on many levels: Workflow can be interrupted and the controlled environment inside your cleanroom can be compromised by an excess of entries and exits. Therefore, proper planning of the compounding day, including stocking of the basic necessary supplies inside the rooms, should be discussed with all compounding personnel to keep entries and exits to a minimum. In addition, your compounding personnel will likely maintain a higher level of accuracy and output of preparations if they have outside support personnel moving supplies and components to them.

Careful review of the type and amount of documentation required inside cleanroom areas should also be considered. Paper documents are notorious particulate generators. Particulates must be reduced whenever possible, so with this in mind, whenever possible, limit the amount of paper used in the cleanroom.

Gowning and Gloving

Among the most costly elements of running a cleanroom are gowning and gloving supplies. Basic training of personnel must include the proper sequence and methodology of effectively donning the proper garb for compounding,

including re-garbing and re-gloving when they renter the cleanroom. At the same time, it should be impressed upon the personnel that each time they leave and renter the cleanroom, there is an associated cost for the supplies used to glove and garb. So, for both quality and economic reasons, entries and exits from critical environments must be kept to a minimum. Reorganization or clear establishment of the gowning area is essential to this process and will emphasize to all compounding personnel the critical nature of this task.

Pass-Throughs, Carts, and Casework

Making maximum use of "material only" pass-through chambers is a key part of a strategy to reduce cleanroom exits and entries. The use of dedicated cleanroom bins, for both the organization and storage of supplies in the rooms and to move compounded preparations out of the rooms quickly and safely, can drastically improve workflow.

A natural complement to any workflow strategy, the use of dedicated cleanroom and anteroom carts that work with your product transfer bins can effectively move compounded preparations out of the cleanroom and move compounding components into the rooms. These cart and bin combinations should be readily recognizable and assigned to specific areas within your cleanroom complex. Carts and bins should never do "double-duty", and should always be routinely cleaned and sanitized. Broken or worn carts and bins should be discarded and replaced.

Historically, it was acceptable for all compounding-related activities to be carried out inside the critical compounding (ISO Class 5) area. Now it is known that completion of pre-compounding activities and documentation duties should not happen inside these critical areas, because of their potential for introduction of particulates and contaminates into the critical compounding environment. That is why it is now routine to have a wheeled cart adjacent to these critical areas for use by personnel to complete documentation and assist in keeping the materials brought into the critical area to a minimum. Assignment of such a cart to each person compounding in your cleanroom will also serve to better organ-

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ize their work and decrease the potential for breaks in aseptic technique that the introduction of this type of ancillary supplies can cause. It cannot be overstated that the proper selection of the casework and carts both inside and outside your cleanrooms can have a significant impact on the daily level of preparations that the cleanroom personnel can compound.

Automated Compounding Devices

Most manufacturers of automated compounding devices (ACDs) have suggested minimum spatial requirements for the proper and efficient use of their devices, usually expressed in linear feet. Planning for these devices and their minimum space requirements when laying out your cleanroom work benches or hoods will both increase staff productivity and decrease the potential for compounding errors due to overcrowding.

Cleaning and Sanitization

As with any consumables, cleaning products should fit the needs of your operation and be stocked for easy access in sufficient quantities near the cleanroom complex. Once cleaning procedures and protocols have been established and in-serviced to your staff, any deviations from their routine should be strongly discouraged. Proper inventory management in this area will discourage any potential for problems caused by improper or inadequate cleaning due to the substitution of any unauthorized or improper agents or supplies.

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Summary

Careful examination of your pharmacy's basic workflow, integrated with solid personnel training and adequate policy and procedure for the safe operation of your cleanroom, is the foundation of a good quality mosaic. It is this foundation that will assure your sterile products program will yield safe and high-quality preparations for your patients. These sometimes-subtle changes can be made when appropriate and need not wait to coincide with an extensive cleanroom remodeling or building project. At its foundation, USP <797> is meant to ensure that compounded sterile preparations are of the highest quality. These standards are also meant to prevent harm as a result of contaminated compounded preparations. As health care providers, we must continuously attempt to improve the products and services our patients receive and move the profession forward, never deferring until tomorrow what can easily be done today. ■

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