Photo courtesy of Q.I. Medical, Inc.

By Holly Simmons, RPh

The Importance of **Proper Aseptic Technique**

USP CHAPTER <797> IS A MULTIFACETED DOCUMENT, PROVIDING RECOMmendations for facility improvements, policies and procedures, operational processes, and quality assurance methods and standards. With improved patient safety as the goal, each of USP <797>'s recommendations and requirements is equally important. Meeting the physical facility standards may require necessary, but expensive, improvements, and many pharmacies are waiting to implement all operational process changes until after their remodel is complete. However, pharmacies should begin to increase quality now, simply by becoming more diligent in staff supervision and quality assurance activities. Specifically, aseptic technique can be taught and evaluated at any organization that prepares CSPs. Compounding facilities must meet the requirements in USP <797>, but if personnel do not follow the correct processes for materials movement and proper aseptic technique, the value of a physical facility remodel will be minimized.

Pharmacies that prepare CSPs can begin to make positive changes to aseptic processes immediately. Robust aseptic technique encompasses not only the manual manipulation of equipment, vials, and syringes in the sterile cleanroom environment, but also proper hand hygiene, garbing, and movement within the compounding area. Even when proper hand hygiene is used, the hands still harbor microorganisms, and a gloved hand is only sterile until it touches a non-sterile surface. Therefore, even when personnel are properly garbed, touch contamination is a potential source for CSP contamination. That said, proper aseptic technique can greatly reduce the possibility of touch contamination.

Photo courtesy of Lab Safety Corporation

Media can be obtained from several vendors in **convenient kits**, or organizations may purchase the media separately and make kits to match their processes.

Photo courtesy of Hardy Diagnostics

The Importance of Training

Many pharmacies struggle with a lack of appropriate training in aseptic technique, and those deficiencies can negatively affect the sterility of pharmacy-prepared CSPs. Various videos and online training programs are available to provide an overview of aseptic technique and proper movement within a cleanroom facility. (See "Where to Find Training Programs" on page 4.) However, while these resources are certainly valuable, they should not be the only tools used to assure that employees are competent in their sterile compounding activities. Management (or a qualified designee) should observe and review aseptic technique for all employees who prepare CSPs. Reviews should be documented at least annually, but should be ongoing and include observation of, at a minimum, the following aspects of aseptic technique:

- Proper hand hygiene
- Proper donning of garb, including shoe covers, beard covers (where applicable), head covers, face masks, non-shedding gowns, and sterile gloves
- Proper movement of compounding materials and medications (How do they get to the laminar airflow workstation or biological safety cabinet? Are the exterior portions of containers wiped down with suitable disinfectant prior to compounding? Does the employee use correct manual manipulations and always avoid blocking the HEPA-filtered air?)
- Aseptic media-fill process simulation

Managers and supervisors should regularly observe each member of the compounding staff, including pharmacists and technicians, to assure that proper technique is maintained. The cleanroom work environment should foster a collaborative atmosphere, in which employees can critique each other's technique without fear of retribution.

Media-Fill Process Simulation

One quantitative tool that can be used to evaluate aseptic technique is process simulation using trypticase soy growth media, or "media fill" testing. The tryp-

ticase soy media promotes bacterial growth and is available in sterile liquid and powder forms, as well as non-sterile powder. The sterile liquid and powder media, when substituted for actual drugs and diluents, can be used to simulate the preparation of low- or medium-risk CSPs, and the non-sterile powder can simulate a high-risk CSP preparation. Media can be obtained from several vendors in convenient kits, or organizations may purchase the media separately and make kits to match their processes.

USP <797> currently requires all employees that prepare CSPs to perform a media-fill activity, at minimum, once annually for low- and medium-risk compounding and twice annually for high-risk compounding. However, many organizations choose to conduct media-fill activities on a more frequent basis. The media-fill activity should closely resemble actual compounding steps and should match the organization's USP <797> risk level. For example, a pharmacy that performs medium-risk level compounding should simulate their most challenging multi-step medium-risk activity, rather than a simple reconstitution and transfer.

After a CSP is prepared with trypticase soy media, it is then incubated at 30 to 35°C for 14 days. If bacterial contamination is present at any time during the incubation period, the solution will appear cloudy or turbid, indicating a "positive" media fill. Each organization must have a written policy describing media-fill activities, logs for documentation of results, and an action plan in place for employees that have a positive media fill.

Ensuring Employee Competency

Upon hire, all pharmacists and technicians should be required to go through an intensive, documented orientation program, which includes training in aseptic technique and the use of media-fill process simulation. Do not assume that new hires know correct aseptic technique just because they have prepared CSPs elsewhere. All employees who compound should be comfortable with the observation process and should know that they will be assessed on a regular basis. After all, this is not about protecting egos; it is about patient safety. Often, when pharmacists or technicians are asked if they would want to be a patient in their own facility, or have a loved one receive CSPs that have been mixed in their facility, they have to pause before answering, because there are some doubts. Every pharmacy manager should ask this of his or her staff.

Pharmacy managers need to closely watch their compounding staff. Let them know that you are involved. If you personally do not prepare CSPs as part of your job, consider doing it on an occasional basis – at least for the critique by others of your aseptic skills. Pharmacists who directly supervise compounding employees should adhere to the same requirements that their compounding staff are required to meet, even if they do not staff the cleanroom on a regular basis. This involvement will garner respect from employees and will also ensure that the supervisor is "kept in the loop" regarding compounding activities.

When employees are in full compounding garb, they may develop a false sense of security, and as such, your staff may not realize that the ways they move and touch materials have a significant effect on the sterility of the end product. Many pharmacy schools and educational programs lack appropriate "hands-on" training in aseptic technique; therefore, many pharmacists do not even recognize that they may be lacking the proper skills to maintain sterile airflow to the critical sites of vials, syringes, tubing, and so on that are being used to mix CSPs. The next time you compound medications (or observe your staff), take great care to observe what the hands and gloves touch, from hand washing to the compounding of medications. Furthermore, ensure that employee's gloved hands are disinfected with 70% isopropyl alcohol on a regular basis.

It is also important to note if vial and syringe manipulations in the sterile environment block the "first air" (HEPA-filtered) within the laminar airflow workstation (LAFW) or biological safety cabinet (BSC). For example, it is a common misconception that, when working in a horizontal LAFW, the mechanics of the manipulations made with hands and arms are not as important if the staff member is working within the area that begins 6 inches inside the hood. While it is true that manipulations should be made at least 6 inches from the outer edge in a horizontal LAFW, it is essential that nothing pass between the critical sites of vials and syringes and the HEPA filter. Also, compounding staff should never lean their heads into the work area of the hood or lay their arms and elbows on the compounding work surface. Additionally, they should not manipulate the vials and syringes in a manner that blocks consistent airflow to critical sites. When corrected, employees often do not realize that they were doing so or that they were not following proper aseptic technique.

Pharmacists and technicians are human, which means we will occasionally make mistakes and can easily fall into bad habits, especially if we are not constantly diligent. The concepts presented here may seem simple at first glance, but are the first line of defense in preparing CSPs that are free from contamination. Physical facility changes and the other areas of USP Chapter <797> are extremely important and necessary, but the way that staff uses the new facility is equally important. Proper aseptic technique is the first "building block" to reducing the possibility of contaminated CSPs and, therefore, reducing the potential for patient harm. ■

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WHERE TO FIND Training Programs:

Basics of Aseptic Compounding Technique Video Training Program	www.ashp.org
Safe Handling of Hazardous Drugs Video Training Program	www.ashp.org
Compounding Sterile Preparations 2.0: A Multimedia Learning Program	www.ashp.org
CriticalPoint E-learning Modules	www.pppmag.com/cp
Valiteq Five-Part Training Video	www.valiteq.com

WHERE TO FIND Media-Fill Testing Kits:

Vendor	Reader Service Number	Website
Lab Safety Corporation	19	www.valiteq.com
Hardy Diagnostics	18	www.hardydiagnostics.com
Q.I. Medical Inc	16	www.qimedical.com