By Kate Douglass, MS, RN, APN,C, CRNI

Facilitating A Quality Culture Through **Effective Staff Training and Competency Assessment**

Though there are many tools available to pharmacies to facilitate best practice in sterile compounding, an empowered and knowledgeable workforce is by far the bedrock of any truly successful operation. Sterile compounding is a complex process where many smaller steps, each performed correctly, culminate to reduce the risk of error and contamination. There is no amount of managerial oversight that can make up for a staff that has not been adequately trained. Only a staff that embraces the rationale behind policy and procedure decisions and understands the impact that each member has on every compounded sterile preparation (CSP) can ensure consistent, high-quality output.

At the STAR Center, Baxa offers hands-on courses in sterile compounding.

Image courtesy of Baxa Corporation

USP Chapter <797> and the standards of the Pharmacy Compounding Accreditation Board have both addressed requirements relative to personnel training, competency assessment, and verification. Dedicating the time to plan and execute effective staff training and development is challenging, but has been reported to pay obvious dividends.[1] Money spent to build the best cleanrooms and provide the compounding equipment is wasted if your staff cannot use these tools correctly. Staff must be knowledgeable of the fundamental principles of compounding and familiar with pharmacy-specific policies that have been developed using credible literature to reflect the activities performed in the pharmacy. The time spent developing an effective orientation and ongoing staff development program, including meaningful and objective competency verification, is the key to achieving an operation that is in control and consistently provides CSPs that are safe for your patients.

Organization-Specific Policies and Procedures: The Foundation of Training

Before training can even be developed, well-defined, detailed policies and procedures must be in place, and training must be consistent with those procedures. Though policy and procedures templates are available for purchase, use them only as a foundation for a customized set of policies and procedures that make sense for your facility's operations and business model.

Each pharmacy's policies and procedures should be unique and based on its operations, goals, deliverables, applicable requirements of law, and standards from relevant accrediting and professional groups. Policies should not merely sit on a shelf in your office; a detailed set of policies and procedures that reflects how activities should be performed at your pharmacy can form the basis of an effective training program. In fact, employees can be trained directly from the policies, and competency assessment and verification forms can be created from your policies and procedures. Policy-based training can ensure that your staff knows the "why, who, what, and when" of compounding-related activities. You should also establish a policy that addresses the orientation and training of new staff members, as well as ongoing staff development, in order to consistently cover all required generic knowledge, as well as verify the compounding knowledge and behaviors specific to each defined role within the pharmacy. Figure 1 represents a proposed process flow for the design of sterile compounding orientation, training, and competency verification programs.

Training Methods

In order to make learning experiences more valuable for your staff, consider the following key characteristics of adult learning[2] as they relate to your staff:

- Your staff will want to know why they need to know information.
- Your staff may only be ready to learn once they decide they need the information to help them with real-life situations.
- A practical application of information to everyday situations is more likely to elicit a positive response from your staff.

Fortunately, technology is currently available to aid pharmacies in providing cost-effective and high-impact compounding education. With the advent of distance and e-learning applications, providing adult-oriented education is easier than ever. Computer networks, learning management systems, and software have made it possible for every pharmacy, large or small, to provide training that is consistent with adult learning models. Computer-assisted learning (CAL) presents the following advantages:

- Staff can use downtime more effectively.
- Staff can review the material at their own pace, so it accommodates high performers as well as novice learners.
- Staff may feel "safer" and consequently learn more, because there is less pres-

sure to perform.

- Staff may find it more "fun" than paper-based learning.
- Staff may take the opportunity to view the learning modules at home on their own time.
- Depending on the application used, recordkeeping is automated.
- Time is saved because objective testing is automated.
- Managers can run learning activity reports, and e-mail functions may remind learners of required modules.
- Material is presented in a consistent manner, eliminating differences attributable to the teacher.

Whether you create your own computer-based training program or you purchase a commercially available program, by utilizing the computer, you have the opportunity to increase the quality and efficiency of staff training.

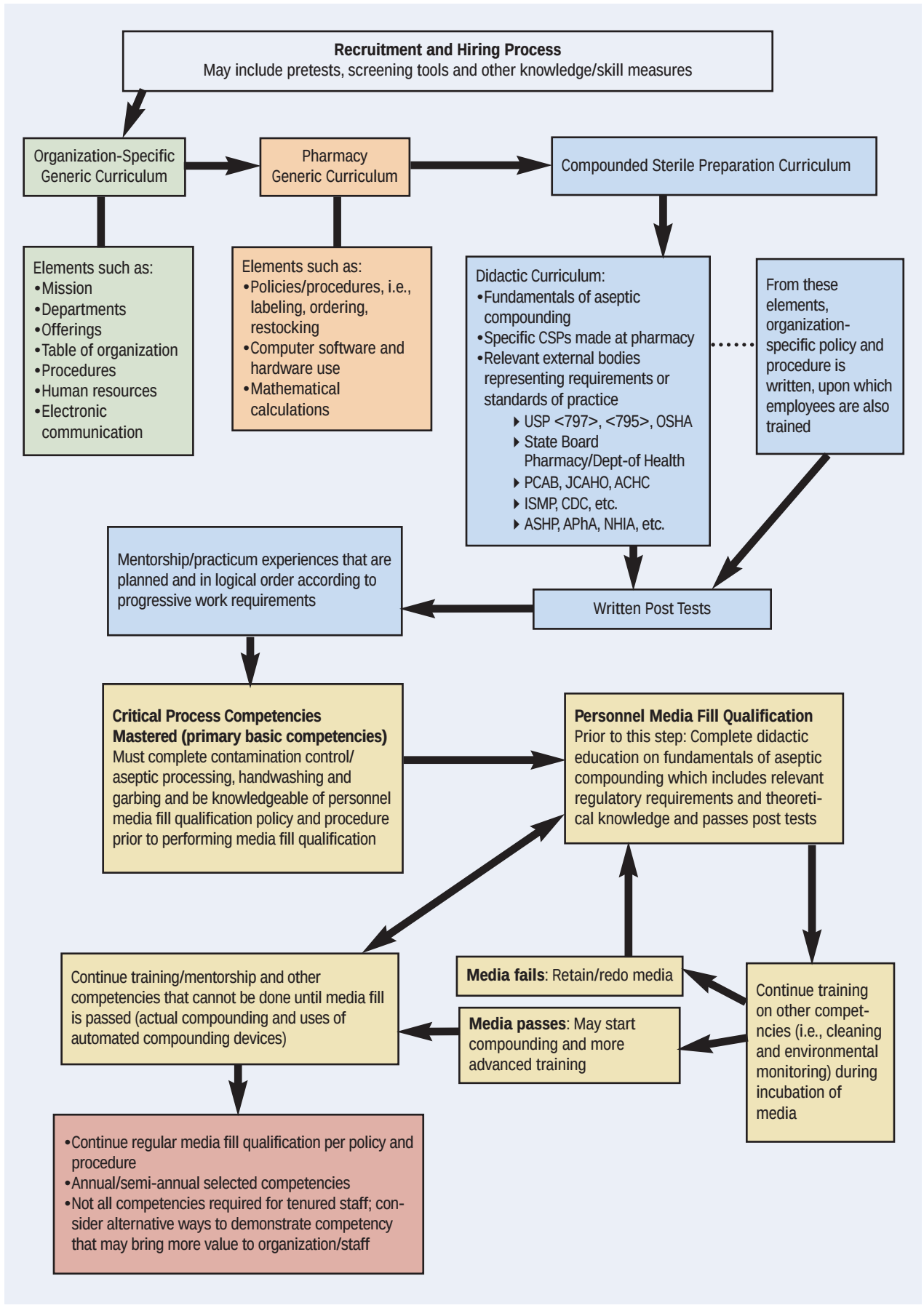
Training Resources

Excellent resources have been developed to specifically address sterile compounding in a variety of formats, including on-site training, hands-on classes, CAL, DVD/VHS/workbooks, and computer applications. One example of a hands-on course is the "Compliance Tools and Certification Training Program for USP <797>" held at Baxa Corporation's Star Center. This comprehensive program is held at a state-of-the-art facility designed for cleanroom and pharmacy practice demonstrations, and combines both didactic and practicum experiences. These courses are excellent for those with little cleanroom background and can serve as a review for a pharmacy's "master" compounders.

Computer-based training modules have also recently been made available by CriticalPoint, LLC. Their Web-based offering includes 32 one-hour segments covering all aspects of sterile compounding with content that is updated as the USP Chapter <797> evolves. It is housed in a learning management system that provides automated documentation of learning activities to improve administrative oversight of personnel training.

Computer-based quality management system applications such as Simplifi <797> from Pharmacy OneSource and the

Figure 1. Process Map for Orientation, Training and Ongoing Staff Development



Valiteq Data Management System software are also available. These applications provide template policies/procedures, core competencies, and automated management tracking and documentation of all cleanroom quality assurance activities.

Lab Safety Corporation offers a variety of training resources, including a DVD, a manual, and the Valiteq Data Management System (DMS) software.

Though all of these training resources require some capital expenditure, they quickly pay for themselves. Instead of spending time developing training programs, pharmacy directors and managers can direct their efforts towards reviewing quality assurance data, routinely mentoring staff, and refining organization-specific policies and procedures.

Pharmacies can also develop their own training materials. However, this takes time and, given the availability of high-quality training resources, a combination of internal and external course material is often the best choice, so long as the education provided is consistent with your pharmacy's policies and procedures. A combination of classroom, computer-based training, and hands-on learning, as well as on-the-job mentorship, can ensure that your staff learns the material effectively.

Competency Assessment

It is necessary to develop objective measurements for the competency of each staff member's compounding skills, as well as to document the outcomes of competency assessments. An individual competency checklist, such as the one illustrated in Figure 2, can identify processes that are critical to sterile compounding. These check-

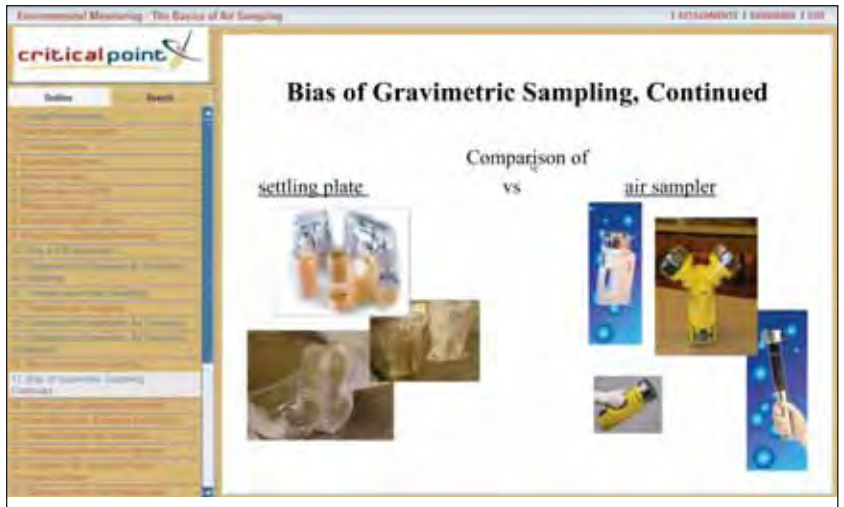


Image courtesy of Critical Point, LLC

Critical Point's 32 computer-based training modules are housed in a learning management system that provides automated documentation of user activities.

lists should reflect both knowledge and psychomotor skills, and should be developed directly from your pharmacy's policy, reflecting any specific procedures.

Remember that competency assessment, as well as knowledge and performance development, are ongoing processes. Desired competencies will change as your staff members and your organization evolves. Therefore, you should measure your new employee's technical skills and develop ways to measure expert-level competencies for more seasoned staff members as well.

Summary

A thorough CSP training and competency program should be developed in an organized and consistent manner and be based on organization-specific policies and procedures. Furthermore, a consistent staff education and development program, involving the entire pharmacy team, can provide excellent feedback for the continual development of policies and procedures and targeted training and development[3]. By using high-quality training resources supplemented with internal course material, you can ensure that your staff members learn and excel at compounding practices and that your patients receive the highest quality CSPs possible. ■

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References:

1. Gregoire JA, Cohen MP. Why didn't I think of that? A sterile products training program: focusing on comprehension, compliance, consistency, and communication. *Pharm Purch Prod*. 2005;2(2):32.
2. Knowles M. *The Adult Learner*: A Neglected Species. 4th ed. Houston: Gulf Publishing Company; 1990.
3. Trapskin PJ, Reagan R, Hite K, Armistead JA. The implementation of a personnel training and assessment program for new standards in the US Pharmacopeia General Chapter <797> Pharmaceutical Compounding of Sterile Preparations. *Hosp Pharm*. 2006;41(1):43-48.

Figure 2. Sample Competency Checklist

Personnel Hygiene, Handwashing, Garbing and PPE

Hospital/Pharmacy Name:	**Unit/Facility:**
Employee Name:	**Date of Assessment:**
Type: ☐ Initial ☐ Retest ☐ Annual review	**Competency Reviewer:**

Knowledge Competencies	Complete Mastery	Incomplete Mastery	Relevant Comments by Reviewer (Must indicate plan for review if incomplete mastery is indicated note activity limitations, if any)
1. Describes how and why hygiene, handwashing, garbing and use of Personal Protective Equipment protect the compounding environment and the compounding operators.			
2. Describes why particle limitation is important in reducing bioburden.			
3. Identifies where garb is kept and action to take if necessary garb is not in proper location.			
4. Articulates appropriate clothing to be worn under garb and into clean area/buffer zone per institutional policy.			
5. Describes procedure to follow if visitors want to tour inside controlled environments.			
6. Articulates policy regarding when safety glasses must be used and why.			
Skill Competencies: ***Employee is observed during garbing and handwashing procedure***			
1. Does not wear cosmetics or hand or wrist jewelry.			
2. Nails are not excessively long. Artificial nails are not worn.			
3. Long hair is tied back.			
4. Does not bring food or drink inside controlled environments.			
5. Removes extraneous personal clothing (scarves, vests, sweaters, hats, etc) and wears clothing that is consistent with established policy.			
6. Dons shoe covers one at a time stepping over the line of demarcation one foot at a time as booties are placed on feet.			
7. Puts on bouffant cap with hair completely covered and inside of cap.			
8. If facial hair, dons beard cover.			
9. Dons face mask covering from bridge of nose to below chin and secures properly.			
10. Puts on safety glasses, if required. Best practice is to require safety glasses at least during mixing of cleaning agents and cleaning procedures when risk of splashing chemicals into eyes is greatest.			
11. Uses lint free wipes/hand dryer to dry hands thoroughly.			
12. If a faucet is not controlled by hands free device, water is turned off using lint free wipe.			
13. Selects gown and cuts hole in cuff for thumb placement to ensure that sleeve does not ride up above gloves.			
14. Dons gown and closes fasteners completely.			
15. Selects appropriately sized gloves so that fingers fit tightly and there is tight fit.			
16. Pulls cuffs of gloves up over the cuff of gown so that there is no gap. Note this is either done in the anteroom or inside the clean room based on institutional policy.			
17. Enters clean room/buffer zone and resanitizes gloves with designated agent before entering ISO Class 5 zone to compound.			
18. Gloves are routinely resanitized whenever the operator removes hands from the ISO Class 5 environment. Designated agent for resantizing must be exposed to all glove surfaces and allowed to dry before compounding resumes.			
19. Gloved hands are routinely inspected for punctures, tears or excessive wear and changed immediately.			
20. When exiting clean room, removes gown, mask, bouffant cap, beard cover, safety glasses, gloves while in the "clean" side of the anteroom.			
21. Retains gown and marks with initials on inside collar and hangs in designated location if permitted by institutional policy if gown is not visibly soiled and is intact. Gown may be reused by that operator for compounding day only.			
22. Retains safety glasses in pocket of labeled gown or other designated location in the "clean" side of the anteroom.			
23. Removes shoe covers one at a time ensuring uncovered foot is placed on the "dirty" side of the line of demarcation and discards.			

Final Assessment of mastery for this competency set: ☐ Complete Mastery ☐ Incomplete Mastery

General comments: Unless noted above, if incomplete mastery is noted, document plan for remediation with specific time deadlines and any activity restrictions which must be observed until mastery is achieved:

This checklist is available online at www.pppmag.com

findit
findit.pppmag.com

WHERE TO FIND: Sterile Compounding Training Resources

www.findit.pppmag.com

Vendor	Reader Service Number
Hands-On Training Courses	
Baxa Corporation's STAR Center	85
Parenteral Medications Laboratories	86
Computer-Based Training and Distance Learning	
ASHP	**88**
CriticalPoint, LLC	**89**
PassAssured, LLC	**91**
Computer-Based Quality Management Systems	
Lab Safety Corporation/Valiteq	**61**
PharmacyOneSource	**92**
Other Training Resources	
Lab Safety Corporation/Valiteq	**93**