Chapter 30

Personnel Training and Competency Evaluation

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Introduction

Contact or touch contamination is the primary cause for microbial contamination of compounded sterile preparations (CSPs).[1,2] USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations recognizes and requires that all compounding personnel must be properly trained and evaluated in their knowledge of the USP Chapter <797> standards, proper aseptic manipulation skills (aseptic technique), personnel cleansing and garbing, and cleaning and disinfecting to prevent and minimize the risk of contact contamination of CSPs both within and outside International Organization for Standardization (ISO) Class 5 areas.[3]

Personnel Training

All personnel who prepare CSPs must be trained and knowledgeable in aseptic manipulations and achieving and maintaining ISO Class 5 environmental conditions before compounding sterile preparations for patients. There are several training options to learn these skills and information; however, a combination of written information, audiovisual aids, and hands-on training by expert professionals is preferred. Several pharmaceutical chemical wholesalers, pharmacy-based companies, and professional pharmacy organizations offer training classes, seminars, and formal programs to train pharmacy personnel in sterile compounding skills.

The first step in the training process is to have the trainee read USP Chapter <797> and USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings.[4] These chapters are very extensive, and the trainee may need to read them several times to understand all of the requirements and principles. It is important for personnel to have this knowledge base and understand the theoretical principles before attending a formal

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training program and learning the practical skills. Most training programs and seminars require the participants to read them and pass a written exam prior to attending the live program.

When choosing a professional training program, make sure that the focus is on USP Chapter <797> and USP Chapter <800> and is accredited through the Accreditation Council of Pharmacy Education. Several professional organizations (e.g., American College of Apothecaries), pharmaceutical chemical wholesalers (e.g., Letco Medical, Medisca, Fagron, and Professional Compounding Centers of America), and consultants (e.g., Critical Point) offer live training courses for sterile compounding and hazardous drug (HD) compounding with a focus on the USP standards. If the facility is a 503B outsourcing facility (Chapter 32), the training program should focus on the current good manufacturing practice (CGMP) regulations, primarily focusing on Code of Federal Regulations Title 21 Part 210 and Part 211. These regulations are posted on the U.S. Food and Drug Administration's website.[5] Although the USP standards and CGMP regulations have similarities, they are specific for the practice setting (503A or 503B), so the appropriate material for the practice setting must be taught.

Many health systems have also developed in-house training programs in addition to using formal published training programs such as ASHP's *Basics of Aseptic Compounding Technique Video Training Program* (Chapters 23 and 24).[6] In-house training programs can be more cost-effective for the health system and can be tailored to meet its specific needs. An expert trainer, such as an education coordinator, manager, or supervisor should be on-site to train the personnel. The site may have one expert trainer for both sterile and HD compounding or there may be a specific trainer for each type of compounding. Personnel must be trained and demonstrate competency in sterile and HD compounding before any compounding may occur. The expert trainer for handling HDs must understand the following:

- Rationale for risk prevention policies
- Risks to themselves or others
- Risks of noncompliance that may compromise safety
- Responsibility to report potentially hazardous situations to management
- Monitoring the environment
- Maintaining records of testing and sampling

Written Assessment of Knowledge

After they have read the standards and regulations and had didactic training, personnel should be given a written exam to determine their level of understanding. Although the USP does not state what is considered a passing grade on a written exam, this author believes that personnel should pass the exam with an 80% or higher score. Personnel who fail the written exam must immediately be reinstructed and reevaluated by expert compounding staff to ensure that the person understands the material and corrects all aseptic practice and/or HD handling deficiencies.

The written exam should be developed so that it actually assesses personnel knowledge of sterile compounding and is not riddled with trick questions or double negatives.[7] There should be a clear and concise answer for each question. Avoid answers such as "all of the above," "none of the above," and "both a and b." Make sure that the answers are objective and not subject to interpretation by the examiner. A good exam reflects the learning objectives of the instruction. Use terms that are used in the USP standards or CGMP regulations to be consistent. Fair test questions should have the following:

- Reflect the learning objectives of the written materials and training
- Show what trainers expect of personnel
- Present each test item as a clearly formulated task
- Prevent one question from aiding in answering another question
- Allow ample time for completion of the test
- Assign test question points before the test is administered

All personnel must pass the written test initially. Annually, personnel must perform a didactic review and pass the written test for both sterile and HD compounding. These tests should be