Exploring the Basics of Sterile Compounding

Chapter 1:  
Sterile Compounding as a Pharmacy Technician

Chapter 2:  
The Sterile Compounding Environment

Chapter 3:  
Sterile Compounding Supplies

Chapter 4:  
Medication Orders and Labeling

Chapter 5:  
Calculations for Sterile Compounding

Early Pharmacy as Art

We can trace the origins of pharmacy back to the earliest civilizations, when the women and men who were healers in their communities used local flowers, herbs, and other natural substances to treat illness and disease. Varied cultures from every continent have long demonstrated an understanding of the healing properties of such materials, as supported by the numerous archaeological digs that uncovered ancient writings, tools, and instruments related to healing work.

Evidence of pharmaceutical compounding can also be found in the stories of several religious traditions. Ancient Islamic texts tell of the medicinal properties of plants and the use of various chemical compounds to promote healing. The excavation of numerous Egyptian tombs provides evidence that religious ceremonies, such as burials, used compounded ointments, salves, and perfumes. The Christian Nativity story is another example of the link between religion and the origin of pharmacy. This story includes a wise man who gifts the healing substance myrrh to the baby Jesus. Myrrh is still used today as a homeopathic treatment for inflammatory conditions of the mouth and gums, and to treat chronic cough.

As world cultures developed due to expanding opportunities for travel, information gleaned from focused study, and increased cross-cultural communication, practitioners took advantage of a widening variety of plants, herbs, and other medicinal compounds. Their careful work, artfully combining the products of the natural world into helpful compounds, gradually developed into the healing art known today as pharmacy.

Some notable people who have been instrumental in the creation and development of pharmacy include the Greek physicians Hippocrates (ca. 460 BC – ca. 370 BC) and Galen (AD 129 - AD 216). Hippocrates is often referred to as “The Father
of Medicine” and is credited with encouraging a scientific approach to medicine and pharmacy, helping to debunk early myths that illness was caused by evil spirits. Galen is commonly known as “The Father of Pharmacy” for his efforts to systematically classify the pharmaceuticals used to treat illness and disease. Works of historic Greek literature, such as The Iliad and The Odyssey, tell the tales of some of the women who were instrumental in the development of ancient pharmacy. For example, Agamede, Princess of Elis, was a well-known healer who used herbal compounds and medicinal tinctures to treat soldiers wounded in the Trojan War.

“Modern” Pharmacy as Science
Since the time of Hippocrates, the practice of pharmacy, remarkably, remained relatively unchanged for about 2,000 years. And even though medical researchers and practitioners made many advances in medicine during the eighteenth century, these advances did not significantly affect pharmacy until the mid-nineteenth century. After about 1850 and since the important discoveries of Dr. Joseph Lister and Louis Pasteur, pharmacy has been advancing at a relatively steady rate. In 1867, Joseph Lister determined that hospital deaths would decrease significantly if personnel thoroughly cleaned surgical instruments and environments before using them. In the 1870s, Louis Pasteur’s work with germ theory led doctors to realize the importance of hand washing and proper sanitization in preventing the transmission of disease. In fact, “modern” pharmacy arises because Lister’s and Pasteur’s work led to the development of procedures and techniques that eventually expanded to become the sterile compounding and aseptic technique practices of today.

Currently, pharmaceutical science combines an understanding of chemistry, botany, and herbology to discover and synthesize the medications that treat patients with a multitude of conditions. Pharmacists and pharmacy technicians work with physicians, nurses, and other healthcare practitioners to dispense medications that treat illness, injury, and disease. Compounding practices have evolved from the creative, but slower, trial-and-error mixing of tinctures, balms, and liniments in the small chemists’ huches of drugstores to the precise sterile compounding performed in today’s sleek, modern pharmacy facilities. But even though pharmacy was first thought of as an art in ancient healing traditions, and then gained more of a scientific and technical framework in the last 150 years, its association as an art remains. In fact, the current edition of Merriam-Webster’s Collegiate Dictionary (in hard copy and on the Web) defines pharmacy firstly as “the art, practice, or profession of preparing, preserving, compounding, and dispensing medical drugs.”

Five Exploratory Labs in Unit 1
Unit 1 of this textbook offers you a basic overview of the origins of sterile compounding and introduces you to the regulations outlined in USP <797>. (Unit 2 guides you through the details of and specific procedures related to USP <797>.) This Unit discusses the proper environment, equipment, and supplies necessary for sterile compounding. It also highlights pertinent terminology and abbreviations.
related to pharmacy practice as well as explaining how to interpret medication orders and prescriptions, verify medication labeling, and do pharmaceutical calculations. The chapters in Unit 1 are ordered to provide a firm foundation of knowledge about sterile compounding basics, with each chapter building on those that precede it.

Each chapter in Unit 1 contains three parts, with an “Exploratory Lab” in Part 2. The exploratory labs are designed to allow you to learn about, understand, and investigate your role, responsibilities, and work environment as a sterile compounding technician. Chapter 1 overviews the origin of pharmacy and the development of practices that eventually led to sterile compounding. It also introduces USP <797> and the core terminology that is used throughout the textbook. Chapter 2 builds upon that foundational information, expanding into the sterile compounding environment and the most important and basic tool of the sterile compounder, the hood. Chapter 3 introduces the additional tools and equipment you will use in sterile compounding. Once you are aware of the tools of the trade, Chapter 4 brings you to the next step: interpreting medication orders and reading pharmacy labels. You then, in Chapter 5, use medication orders and pharmacy labels to determine the pharmacy calculations you will perform during the mixing of compounded sterile preparations (CSPs). Once you have mastered the pharmacy calculations presented in Chapter 5, you will have completed the “basics” section of the textbook and be ready to learn about and practice the pharmacy sterile compounding procedures of Unit 2.
**Learning Objectives**

- Gain awareness of the historical roots of pharmacy and sterile compounding.
- Define sterile compounding and aseptic technique.
- Describe the ways that sterile compounding and aseptic technique processes may affect patient health and safety.
- Define the objectives of USP <797>.
- Understand the training requirements for pharmacy technicians who prepare sterile products, and describe the process validation tool that is used for technique evaluation.
- Recognize various quality assurance and end-product testing procedures.
- Determine appropriate responses to medication safety questions.
- Demonstrate an awareness of the ethical issues in pharmacy.

The art of compounding, or the mixing of several different agents, can be traced back to the ninth century in Mesopotamia and the Middle East. At that time, doctors, midwives, mystics, and learned members of religious orders experimented with chemical processes to create luxury products for religious leaders and royalty. By the Middle Ages, compounding practices had spread to Europe, where craftspeople, or artisans, began combining flowers, herbs, and other natural substances to create medicinal elixirs, powders, and ointments with the power to cure the sick and injured and—many believed—to prolong life.

These skilled compounding artisans were known as *alchemists* and revered by people from all segments of society. These artisans and their compounding pharmacies, or *apothecaries*, sprang up all across the European continent. Their work was frequently rooted in the spiritual beliefs of the time, and sometimes shrouded in mysticism. In fact, many of the compounds that alchemists prepared were thought
to have magical properties. Such early pharmacy practitioners were quickly associated with their main tool for grinding and mixing the ingredients by hand: the mortar and pestle.

The start of the Industrial Revolution, which began in Great Britain but quickly spread to the United States, changed the practice of compounding from a hands-on art to a science in the late 1800s: Automated machinery produced great volumes of syrups, elixirs, powders, and other drug forms with increased speed. Yet despite the advent of pharmaceutical manufacturing, pharmacists continued to use their knowledge of compounding for eighty percent of the prescriptions they filled. While they incorporated the mass-manufactured ingredients, they still needed to perform many compounding tasks in order to fill a prescription written by a physician. Many pharmacists continued to roll their own pills and formulate their own liquids and powders and, like their artisanal predecessors, turned to the healing powers of nature. They used plants such as belladonna (for headaches), foxglove (for heart ailments), bloodroot (for throat infections), and St. John’s Wort (for burns) in their compounding preparations. Thus, apothecaries thrived well into the nineteenth century as people continued to rely on the potions and cures of these mystical chemists.

But by the mid-twentieth century in all areas of the world, pharmaceutical compounding became less and less common in a pharmacist’s daily practice. Relying on large manufacturing plants, pharmaceutical manufacturers synthesize drugs into stable, uniform, high-quality medications in various dosage forms—primarily oral solids, oral liquids, and topical preparations. The capacity of such plants enabled more drugs meeting federal standards for purity and quality to be available for more patients in the U.S. As a result, pharmacists were compounding only about one-fourth of the total prescriptions that they filled, and their role shifted from both creating and dispensing medications to primarily dispensing them.

However, toward the end of the twentieth century, an increased need for intravenous admixture services, injectable dosage forms, and individualized medications led to a dramatic rise in the number of practitioners and environments involved worldwide in sterile product preparation. These increases came about as physicians recognized the advantages of personalized medication dosing. Such dosing allowed physicians to provide more exact and specialized treatment for the patient. Increased allergic reactions to various inactive ingredients in manufactured drugs, as well as a need to provide medications to patients who were unable to tolerate the oral dosage form, also increased the use of sterile compounding.

Still, it wasn’t until the early 1990s that pharmacy practitioners realized the need to implement safer practices related to sterile compounding and aseptic technique. Independent scientific research had determined that compounded sterile preparations at times provided both a fertile breeding ground for bacteria and a perfect vehicle for transmitting bacteria to the patient recipient. Fortunately, multiple studies recognized that correct sterile compounding practices could play a vital role in protecting the patient from this potential harm.

Today, the practice of pharmacy and the guidelines and regulations under which sterile compounding personnel work continue to evolve. This chapter provides you with an overview of current practices and regulations.
The pharmacy practice of **sterile compounding** involves the dilution, mixing, and injection of various medication products using aseptic technique. **Aseptic technique** is vital to the compounding process in order to avoid the introduction of pathogenic organisms or other contaminants into a sterile environment or preparation. Failure of pharmacy personnel to follow the protocol of aseptic technique may lead to **microbial contamination** of the medication, resulting in serious illness or, possibly, death for patient recipients. Therefore, it is critical for patient health and safety that you, as a pharmacy technician, become well-versed in aseptic technique and the procedures for sterile compounding.

**Roles and Responsibilities of IV Technicians**

Pharmacy technicians play a major role in preparing **compounded sterile preparations (CSPs)** in pharmacies. These specialized technicians—often referred to as sterile compounding technicians, intravenous (IV) admixture technicians, or simply IV technicians—are largely responsible for preparing injectable medications for patients in hospital and home healthcare settings who are unable to swallow or whose digestive systems preclude the use of oral medications.

Technicians prepare injectable medications for those patients whose conditions necessitate a more rapid delivery of medication into the blood supply. These injectable medications may be delivered to the patient via parenteral routes such as **intramuscular** (IM), **subcutaneous** (Sub-Q), **intrathecal** (IT), or **intravenous** (IV).

A majority of the medications that are prepared by sterile compounding technicians are administered through an IV. Often, you dilute a drug in powder form with a solvent such as sterile water or **normal saline** (NS). You then draw the diluted drug into a syringe and inject it into a sterile intravenous piggyback (IVPB) base solution such as **dextrose 5% in water** (D5W). You then inject the final prepared solution through sterile tubing directly into the patient’s vein.

**The Effect of Aseptic Technique on Patient Health and Safety**

Correct sterile compounding and aseptic technique procedures—performed by well-trained personnel in a clean, controlled environment—are essential to patient health and safety. To ensure that these aseptic practices are strictly followed, sterile compounding technicians must undergo frequent evaluation based on such tools as process validation checklists and numerous quality assurance and end-product testing procedures. These safeguards not only prevent medication errors but hold technicians to the highest quality-control standards. Setting these practice standards for the compounding of sterile products is the **United States Pharmacopeia (USP)**. The USP, a nongovernmental regulatory organization, sets public standards for the
Part 1: Concepts

preparation and dispensing of prescription and over-the-counter medications as well as other healthcare products.

**USP <797>**

The USP guidelines are a mainstay for both pharmacists and pharmacy technicians. In particular, Chapter <797> of the United States Pharmacopeia, more commonly known as USP <797>, sets practice standards regarding the preparation of sterile compounds. USP <797> covers topics such as the training and responsibilities of the personnel who prepare sterile products, the storage and importance of beyond-use dating of sterile compounds, quality assurance, and environmental quality control. USP <797> also identifies four specific risk levels for CSPs: **low-risk level, medium-risk level, high-risk level,** and **immediate use**. Each of the risk levels is assigned according to the “potential for microbial contamination during compounding.” (USP <797>, page 7) Within each risk level, the USP designates the types of preparations that may be compounded and the special training and testing required for sterile compounding personnel. Chapter 2 will cover additional information regarding risk levels and the environments that are suitable for sterile compounding.

**Training and Testing Requirements**

To work in a sterile compounding facility in most states, personnel must be certified pharmacy technicians and must undergo additional training and testing on the compounding of sterile products. Every state has its own regulations regarding the training and testing of pharmacy technicians. After years of advocacy by pharmacy technician organizations and pharmacy technician educators, laws are slowly being enacted to provide more standardization in the requirements for pharmacy technician education and training. At a minimum, most states now require that pharmacy technicians pass a national certification exam. Two pharmacy technician certification exams are offered in the United States. The most widely used exam is the **Pharmacy Technician Certification Exam (PTCE)**, offered by the Pharmacy Technician Certification Board (PTCB) and accepted by all of the U.S. Boards of Pharmacy. The **Exam for the Certification of Pharmacy Technicians (ExCPT)**, which is offered by the Institute for the Certification of Pharmacy Technicians (ICPT), is currently accepted by only a portion of the State Boards of Pharmacy.

Regulations regarding the training and testing of sterile compounding technicians are not as well defined. Some of the agencies that develop guidelines for the training of personnel who perform sterile compounding include the Accreditation Council on Pharmacy Education (ACPE), the American Society of Health-Systems Pharmacists (ASHP), the American Pharmacists Association (APhA), and the Board of Pharmacy for each individual state. Many of these organizations refer to USP <797> as a guideline for developing policies related to sterile compounding and personnel training. Another tool that is widely used in the development of comprehensive training programs for pharmacy technicians is the ASHP’s **Model Curriculum for Pharmacy Technician Training**.

It is considered **best practice** that all personnel who prepare sterile products complete an ACPE-certified training program in sterile product preparation and aseptic technique. At a minimum, sterile compounding technicians should either be experienced and knowledgeable pharmacy technicians who have good backgrounds in math and science, or students who have graduated from well-designed pharmacy technician
schools or training programs. It is standard practice that sterile compounding students should receive a minimum of forty hours of hands-on training in a laboratory setting, along with classroom instruction, independent study assignments, written exams, and process validation procedures designed to prepare trainees to work in IV rooms.

In addition, sterile compounding employees should receive a minimum of forty hours of practical training in IV rooms and must pass intensive process validation evaluations and quality assurance testing prior to making sterile products for patient administration. USP <797> requires that sterile compounding personnel undergo annual recertification, which includes a written exam, a process validation evaluation, and the completion of a media-fill kit.

**Process Validation**

Sterile compounding personnel must undergo process validation for each aspect of the training process. During process validation, instructors observe, critique, and grade students’ technique on specialized process validation checklists. These checklists break down each technique into small components that are observable and graded. Some of the techniques evaluated in this way include sterile garbing and gloving, horizontal laminar airflow hood cleaning, vial preparation, ampule preparation, and large-volume parenteral preparation. Chapters 6–14 discuss the process validation checklists for procedural laboratory techniques, and the checklists themselves are located in Appendix E.

**Quality Assurance**

Sterile compounding personnel must also undergo various quality assurance procedures as part of the training process. For instance, students confirm their ability to aseptically don sterile garb and gloves by providing evidence of a negative growth fingertip test. Students must also demonstrate how to properly clean and disinfect a hood, a process that is evaluated by culturing the hood’s surface. As another quality assurance procedure, students must correctly complete an aseptic technique testing kit, also referred to as a media-fill kit, process validation kit, Gro-Med kit, or ATTACK kit. Lastly, end-product testing evaluates a student’s sterile compounding techniques by assessing their prepared products for contamination and also verifying that they contain the proper type and amount of medication.

Before sterile compounding personnel can make sterile products for patient administration, they must complete this type of testing and demonstrate 100% compliance with aseptic technique requirements. In addition, all personnel who prepare sterile products should successfully complete process validation and an aseptic technique testing kit at least once a year. Sterile compounding personnel who fail to demonstrate correct aseptic technique during the annual re-certification process must be offered retraining as necessary. Retraining must also take place any time a pharmacy authority observes a break in technique. The individuals being retrained must then undergo additional process validation and aseptic technique testing in which they must demonstrate 100% compliance before being allowed to return to sterile compounding.

In sterile compounding pharmacies, process validation and other quality assurance testing procedures are critical controls to ensure the safety of the compounding process and the integrity of the end product.
Medication Safety

Quality assurance procedures are critical in every healthcare setting to ensure the safe dispensing and administration of medication to patients. Adherence to these medication safety standards is the responsibility of every healthcare professional. Any breach of these established guidelines could lead to a medication error, any preventable event in which a patient is, or may have been, harmed by a medication. Although every medication order brings with it the possibility of a medication error, healthcare workers who dispense or administer medications must diligently verify the five patient “rights” of correct drug administration: right patient, right drug, right dose, right route, and right time.

Medication errors in sterile compounding pharmacies typically involve incorrect drugs (“right drug” errors) or errors in pharmacy calculations (“right dose” errors). Chapters 4 and 5 provide additional information on how to avoid these types of errors.

Monitoring of Medication Errors

Several agencies and organizations track medication errors with the goal of providing evidence-based information and guidelines designed to decrease the incidence of medication errors. The Institute for Safe Medication Practice (ISMP) is a nonprofit organization that educates the healthcare community and consumers about safe medication practices. The ISMP publishes a list of abbreviations that most pharmacies and institutions want to eliminate from use. MedWatch, a voluntary program of the Food and Drug Administration (FDA), supports healthcare workers in the reporting of medication errors and adverse drug effects (ADEs). The Joint Commission, formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), has several programs designed to decrease medication errors and improve patient safety.

In addition to these regulatory agencies, every pharmacy has its own policies and procedures in place to reduce medication errors and encourage error reporting. To effectively do so, pharmacies must foster a culture of safety. When an error is made, a pharmacy must examine the system that allowed the error to occur, rather than placing blame on the individual responsible for the error. When a pharmacy poses questions that explore the circumstances surrounding the medication error, beneficial changes to pharmacy protocol may result. Some possible questions include: How would you describe the workload in the pharmacy when the medication error was made? What type of distractions might have affected the employee’s performance? Considering the type of error that was made, would better package labeling or bar-coded packaging have prevented the error? By taking this investigative approach to examine the systemic processes that led to the error, pharmacy personnel can discover ways to change their policies and procedures that reduce the likelihood of repeating that type of error.

Ethical Issues in Pharmacy Practice

A number of legal and ethical concerns are related to pharmacy practice. Many center on reducing medication errors and reporting errors that do occur. Each state’s State Board of Pharmacy provides legal guidelines and oversight for pharmacy practice. In addition, most states have regulations defining mandatory error reporting procedures.

Like other pharmacy personnel, pharmacy technicians are legally and ethically bound to provide safe and effective care for the patients they serve. To assist technicians
in fulfilling these responsibilities, the APhA has published the *Code of Ethics for Pharmacy Technicians*. This publication serves as a touchstone for technicians faced with ethical and legal decisions.

## Concepts Self-Check

### Check Your Understanding

Write your answers on a separate sheet of paper, as modeled in these examples: 1d; 2c; 3b; etc. Check your answers using the Answer Key in Appendix A.

1. Sterile compounding technicians do not generally prepare medications that are delivered by which of the following routes?
   - a. IM
   - b. IV
   - c. Sub-Q
   - d. PR

2. Which of the following organizations sets standards for the purity, quality, strength, and consistency of prescriptions and over-the-counter medications?
   - a. ACPE
   - b. ASHP
   - c. USP
   - d. PTCE

3. Which of the following exams are required by most states for the certification of pharmacy technicians?
   - a. either the PTCE or ExCPT
   - b. either the PTCE or the PTCB
   - c. either the ExCPT or the PTCB
   - d. either the ExCPT or the ICPT

4. At a minimum, how often must sterile compounding personnel undergo process validation to show 100% compliance with aseptic technique?
   - a. annually after the completion of initial training
   - b. at the completion of initial training, annually thereafter, and upon evidence of poor technique
   - c. semi-annually after completion of initial training
   - d. at the completion of initial training, and upon evidence of poor technique

5. The primary purpose of the APhA publication *Code of Ethics for Pharmacy Technicians* is to
   - a. explain the laws that must be followed by pharmacy technicians.
   - b. define the ethical responsibilities of pharmacy technicians.
   - c. list the duties of pharmacy technicians.
   - d. discuss the morals that must be followed by pharmacy technicians.

### Expand Your Knowledge

Write your answer to this question on a separate sheet of paper, taking the time to create a thorough and thoughtful response and use complete sentences. Check your answer against the “Possible Answer” provided in the Answer Key in Appendix A.

**Scenario** Correct aseptic technique plays a vital role in patient care and safety. In light of this fact, what do you think you should do if you accidentally contaminate the sterile product in the course of preparing a medication for IV administration?
Examine the Resources and Supplies

USP

Personnel who work in the sterile compounding room must be familiar with the USP. As discussed earlier, in Part 1 of this chapter, pharmacists and pharmacy technicians use the USP as a reference and guide because it offers valuable information on nearly every aspect of pharmacy practice. Pharmacy personnel may refer to the USP to ascertain and develop appropriate policies and procedures for pharmacy operations. It is especially important that personnel who prepare sterile products be familiar with the objectives and content of USP <797>. Sterile products personnel must give special attention to the training and testing requirements of the sterile compounding technician as defined in USP <797> and to the information regarding medium-risk level (the risk-level condition under which most sterile products are prepared). Pharmacy technicians using the USP as a resource will build familiarity with its important contents and gain a solid understanding of why it is such a valuable resource in pharmacy practice.

Process Validation Checklists

Process validation checklists are an important part of aseptic technique training. Each checklist corresponds to a particular aspect of aseptic technique and serves as an evaluative tool for instructors to test students’ competency. Once you become a sterile compounding technician, the process validation checklists continue to serve you as a valuable tool—a study aid to help you prepare for your initial and annual competency tests. Chapters 6–14 contain procedural labs that require your instructor to complete a process validation checklist as you perform the lab. It is considered best practice for you, as a sterile compounding technician, to read the corresponding checklist before you begin the procedural lab and after you complete it. You are also recommended to practice the steps in the procedural lab several times prior to instructor observation for competency evaluation.

Aseptic Technique Testing Kit

Several different types of aseptic technique testing kits are available. These kits are used to confirm sterile compounding and aseptic technique competency, to assess technique failures, and to design corrective actions. The media-fill kit is one of the
most commonly used aseptic technique testing kits
for initial training and annual validation and usually
includes one or more vials or ampules and a small-
volume PVC bag (typically 50 mL or 100 mL) con-
taining a soy broth testing solution. Most of these
testing kits require the technician to make multiple
withdrawals from a vial or an ampule and then make
multiple injections into the bag. You then incu-
bate the bag for the period of days specified by the
product's manufacturer. This soy broth medium is
designed to test the compounders' aseptic technique.
If the person being tested has a break in technique,
the aseptic technique testing kit will indicate that
error in technique by developing visible particles in
the bag, which simulates bacterial growth. Phar-
macy personnel use process validation testing kits to
confirm sterile compounding and aseptic technique
competency, assess technique failures, and design
corrective actions.

**Code of Ethics for Pharmacy Technicians**

Many pharmacy technician training programs develop a code of ethics for pharmacy
technicians. This code of ethics is frequently part of a training program's student hand-
book and is sometimes recited by students during the program's graduation ceremony.
The code outlines and defines the ethical responsibilities of the pharmacy techni-
cian, often including guidelines that promote patient health and safety and encourage
honest and dependable actions by the pharmacy technician. Although a pharmacy
technician program may develop
its own code of ethics, the most
widely used and recognizable
one is the AphA's Code of Eth-
ics for Pharmacy Technicians.
This code defines specific ethical
responsibilities that are the duty
of every pharmacy technician.
Some of the tenets of the code
include integrity, safety, respect,
competency, confidentiality, and a
duty to uphold the legal regula-
tions under which the pharmacy
technician practices.
Exploratory Lab

The purpose of this lab is to examine important resources and tools used in pharmacy practice. This exploratory lab introduces you to the USP and, more specifically, to USP 797. You also investigate the process validation checklists and aseptic technique testing kit, important tools for verifying aseptic technique and sterile compounding competency. In addition, you use the Code of Ethics for Pharmacy Technicians to answer medication safety and ethical questions about pharmacy practice.

Supplies

- USP (text or website)
- Process Validation Checklists (Appendix E)
- Media-Fill Aseptic Technique Testing Kit
- APhA’s Code of Ethics for Pharmacy Technicians

Procedure

Using the USP

1. Open the USP to the Contents page.
2. Answer Question 1 in the Check the Basics section in Part 3.
3. Open the USP to the section on Pharmacy-Related General Chapters.
4. Find the Section Contents page.
5. Find Chapter 797 (official beginning June 1, 2008).
6. Read the information under the heading Organization of this Chapter.
7. Answer Question 2 in the Check the Basics section in Part 3.
8. Turn to the Chapter 797 paragraph titled “Responsibility of Compounding Personnel” and read all of the related information.
9. Answer Question 3 in the Check the Basics section in Part 3.
10. Find the Chapter 797 paragraph titled “Verification of Compounding Accuracy and Sterility” and read the first three paragraphs in that section.
11. Answer Question 4 in the Check the Basics section in Part 3.
12. Temporarily set the USP aside; you will need it to answer Questions 7 and 8 in the Check the Basics section in Part 3.

Understanding Process Validation

13. Open your textbook to Appendix E.
14. Read through each of the process validation checklists in Appendix E.
15. Use the information in Appendix E to answer Questions 5 and 6 in the Check the Basics section below.
**Examining the Media-Fill Aseptic Technique Testing Kit**

16. Open the media-fill aseptic technique testing kit.
17. Explore the contents of the kit.
18. Read the manufacturer's instruction sheet included in the kit.
19. Notice the details of the procedures that will be performed during the preparation of the media-fill aseptic technique testing kit. Note that these procedures must be successfully completed to verify initial and annual competency in aseptic technique and sterile product preparation.
20. Turn to the USP Chapter <797> and read the paragraph on Personnel Training and Evaluation in Aseptic Manipulation Skills.
21. Turn to the USP Chapter <797> and read the paragraph on Media-Fill Challenge Testing.
22. Answer Questions 7 and 8 in the *Check the Basics* section below.

**Making Ethical Decisions**

23. Read the *Code of Ethics for Pharmacy Technicians*.
24. Answer Questions 9 and 10 in the *Check the Basics* section below.

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**Lab Procedure Process Validation Checklist**

<table>
<thead>
<tr>
<th>Step</th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
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</thead>
<tbody>
<tr>
<td>Garbing</td>
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<tr>
<td>Wiped off jewelry up to the elbows.</td>
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<tr>
<td>Wore clean, nonshedding garments.</td>
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<tr>
<td>Did not wear makeup, perfume, nail polish, or artificial nails.</td>
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<tr>
<td>Properly dressed clean clothes.</td>
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<tr>
<td>Properly trimmed hair.</td>
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<td>Properly trimmed face nails or beard area.</td>
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<tr>
<td>Aseptic Hand Washing</td>
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<tr>
<td>Squeezed sponge package before opening to activate soapsuds.</td>
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<tr>
<td>Added water to the sponge as needed to maintain adequate lather.</td>
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<tr>
<td>Used pick to clean under all finger nails before washing and threw away pick after use.</td>
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<tr>
<td>Used brush to clean under finger nails and around cuticles of each nail.</td>
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<tr>
<td>Used sponge to clean all four surfaces of each finger.</td>
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<tr>
<td>Cleaned each finger individually.</td>
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<tr>
<td>Used sponge to clean each of the palms.</td>
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<tr>
<td>Used sponge to clean the back of each hand.</td>
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<tr>
<td>Used sponge on forearms, using a circular motion from wrist up to elbow.</td>
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<tr>
<td>Maintained an appropriate amount of lather during procedure.</td>
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<tr>
<td>Did not touch the sink, faucet, or other contaminated during procedure.</td>
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<tr>
<td>Gowning and Gloving</td>
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<tr>
<td>Opened gown package so that gown remained sterile.</td>
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<tr>
<td>Properly donned sterile gown.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used foamed alcohol to clean hands prior to donning gloves.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Properly donned sterile gloves.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not contaminate gowns, clean hands, or gloves during procedure.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removing Personal Protective Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removed gloves properly.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removed gown properly and place it in the correct location.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removed face mask, hair cover, and shoe covers in proper order.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Score**

| Number of minor infractions (2-point deductions) indicated by a “No” check mark | Points |
| 2-point deductions for minor infractions (2 points × number of minor infractions) | |
| Number of critical errors (30-point deductions indicated by a “No” check mark) | |
| 30-point deductions for critical errors (30 points × number of critical errors) | |
| Total number of points deducted during the procedure (from 100 possible points) | |
| Total Points | |

**Instructor Feedback**
**Part 3: Assessment**

**Chapter Summary**

- Pharmacy technicians play an important role in all aspects of medication preparation and delivery and are a vital member of the healthcare team.
- Most CSPs are administered by the parenteral route.
- Sterile compounding technicians, or IV technicians, use aseptic technique to assemble compounded sterile preparations for administration to patients.
- The USP provides standards and regulations for the preparation and dispensing of medications and healthcare products.
- Technicians must follow USP <797> guidelines for the compounding of sterile preparations and strictly adhere to proper aseptic technique to reduce potential contamination of the CSP by pathogenic organisms.
- Failure to follow aseptic technique procedures may cause harm to the patient, which may result in serious injury or death.
- State requirements vary on the education, training, certification, and licensure of pharmacy technicians.
- Most states require pharmacy technicians to pass a national pharmacy technician certification exam such as the PTCE.
- Pharmacy technicians should complete an ASHP accredited pharmacy technician training program prior to taking the PTCE.
- Pharmacy technicians who prepare CSPs must complete an ACPE accredited training program in aseptic technique and sterile product preparation prior to making sterile compounds for patient administration.
- Many federal and state agencies oversee the practice of pharmacy, including the FDA and the State Boards of Pharmacy.
- Numerous professional organizations, including ASHP, APhA, PTCB, and ICPT, strive to improve knowledge of medication and pharmacy practice, and support pharmacists and pharmacy technicians by advocating for the pharmacy profession.
- Prior to compounding CSPs, pharmacy technicians must undergo rigorous training that should include classroom instruction, independent study, written exams, and multiple process validation evaluations.
- Sterile compounding personnel and the CSPs they prepare must undergo various quality assurance and quality control testing procedures such as the media-fill kit, end product testing, and gloved finger-tip sampling.
- Pharmacy technician training, testing, and evaluation, and quality control procedures help to ensure quality patient care by decreasing the potential for CSP contamination.
- Medication safety is the responsibility of every healthcare worker.
- Verifying the five patient rights of correct drug administration can help to prevent medication errors.
- In the sterile compounding environment, most medication errors involve incorrect drugs or pharmacy calculations.
- Many organizations, including the ISMP, FDA, and Joint Commission, work to decrease medication errors and improve medication safety and also encourage medication error reporting as a vital educational process toward the goal of decreasing medication errors.
- Pharmacy technicians must always act in a legal and ethical manner and may consult the *Code of Conduct for Pharmacy Technicians* when facing an ethical dilemma.
Sterile Compounding as a Pharmacy Technician

Key Terms

adverse drug effect (ADE) any negative, unintended, or unexpected consequence of a drug, which may or may not result in harmful consequences to the patient; also known as adverse drug reaction (ADR) or adverse event (AE)

aseptic technique processes and physical preparation methods used by personnel who prepare sterile compounds; meant to avoid the introduction of pathogenic organisms or other contaminants into a sterile environment or preparation

aseptic technique testing kit uses a soy broth medium and requires the student to perform multiple withdrawals and injections; completed kit is incubated for a period of time specified by the product manufacturer; visible bacterial growth indicates that aseptic technique was compromised at some point during the completion of the testing kit

best practice a requirement, practice, procedure, or guideline that meets or exceeds the highest standards, usually those set by ASHP, that are recognized in pharmacy practice

beyond-use date date or time after which a CSP is no longer sterile, stable, or effective and must not be used; also called the expiration date

Boards of Pharmacy separate entities in each state of the U.S.; create, oversee, and enforce state and federal laws and regulations governing the practice of pharmacy within the state; provides licensure and registration for pharmacies, pharmacists, and pharmacy technicians

break in technique any incidence of failure to follow aseptic technique procedures and protocols; may be observed visually, or evidenced through media-fill, end product, process validation, or other testing

compounded sterile preparations (CSPs) the mixing of one or more sterile products using aseptic technique; subject to extensive USP <797> guidelines for determining the risk levels and appropriate procedures related to their preparation. The risk are designated as:

low-risk level CSPs refers to sterile compounding situations that meet all of the following conditions: compounded entirely within an ISO Class 5 environment using aseptic technique, mixing no more than three commercially manufactured sterile ingredients, and using no more than two injections into any single container

medium-risk level CSPs refers to sterile compounding situations that meet all of the following conditions: compounded entirely within an ISO Class 5 environment using aseptic technique, and involves the mixing of multiple sterile products using complex aseptic manipulations

high-risk level CSPs refers to sterile compounding situations that meet the following conditions: compounding in an environment worse than ISO Class 5, compounding by improperly garbed or gloved personnel, and or compounding involving one or more non-sterile ingredients

dextrose 5% in water (D5W) a sterile solution that contains a concentration of 5% dextrose in water

end-product testing a type of quality control and quality assurance testing in which a CSP is assayed to verify the strength or concentration of its ingredients as well as to determine its sterility. Guidelines for end-product testing and other types of testing are provided in USP <797>

Exam for the Certification of Pharmacy Technicians (ExCPT) offered by the Institute for the Certification of Pharmacy Technicians, a division of Assessment Technologies Institute (ATI); not yet widely accepted as a national certification exam; verify state-based acceptance through your state board of pharmacy

five “patient rights” of correct drug administration right patient, right drug, right dose, right time, and right route; designed to reduce the chance of medication error; every healthcare worker who administers or prepares medications should verify these five rights prior to administering a drug to the patient

Food and Drug Administration (FDA) US Government agency responsible for laws and oversight of all regulations related to the development, manufacture, and labeling of medications within the United States; protects public health and safety by ensuring that food, drugs, and cosmetics are safe, effective, and truthfully labeled

Hippocrates (ca. 460 BCE—ca. 370 BCE) a Greek physician often referred to as “The Father of Medicine”; credited with encouraging a scientific approach to medicine and pharmacy, which helped to debunk early myths that illness was caused by evil spirits (pull if can’t place term in the chapter 1 opener>
immediate use CSPs a risk level intended only for CSPs prepared outside of the pharmacy in emergency situations; administration must begin within one hour of preparation; may not be stored for any length of time

intramuscular (IM) route the injection of a sterile medication into a large muscle such as the gluteus maximus or deltoid muscles

intravenous (IV) route the injection of a sterile medication into the vein

media-fill kit used to evaluate the aseptic technique of sterile compounding personnel; also known as an aseptic technique testing kit (ATTACK)

medication error defined as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer” by the National Coordinating Council for Medication Error Prevention and Reporting; may include errors in “prescribing, order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use”

MedWatch a voluntary program run by the FDA for reporting serious adverse events for medications and medical devices; serves as a clearinghouse for information on safety alerts and drug recalls. (Ballington, 4th edition p. 469)

microbial contamination contamination of a CSP by any microbial organism, bacteria, virus, fungi, or other pathogen; may result in infection or other harm to patients receiving the CSP

normal saline (NS) a sterile solution containing a concentration of 0.9% sodium chloride in water

Pharmacy Technician Certification Exam (PTCE) a nationally accepted certification exam offered by the PTCB; PTCB-certified pharmacy technicians are designated by the acronym CPhT (Certified Pharmacy Technician)

process validation an evaluation checklist that an instructor uses to observe, critique, and grade a student’s aseptic technique during the training period; also used as part of the annual recertification process for sterile compounding personnel as regulated by USP <797>

quality assurance procedures methods and tests for ensuring use of proper aseptic technique

sterile compounding the process of diluting, mixing, injecting, or otherwise preparing sterile solutions using aseptic technique

subcutaneous (Sub-Q) route injection of a sterile medication into the area just beneath the skin; the formerly accepted abbreviations SC and SQ are now discouraged

United State Pharmacopeia (USP) a nongovernmental regulatory organization that sets public standards for the preparation and dispensing of prescription and over-the-counter medications as well as other healthcare products

USP <797> Chapter <797> of the United States Pharmacopeia, which sets practice standards regarding the preparation of sterile compounds

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**Check the Basics**

*On a separate sheet of paper, write your answers as modeled in these examples: 1d; 2c; 3b; etc.*

1. Which section of the USP provides pharmacy-related general chapter information?
   - a. Section 2
   - b. Section 6
   - c. Section 7
   - d. Section 10

2. Which of the following is not listed as a main section of USP Chapter <797>?
   - a. Responsibilities of All Compounding Personnel
   - b. Authorized Monographs Specifically Developed for Veterinary Application
   - c. Storage and Beyond-Use Dating
   - d. A Quality Assurance Program for CSPs

3. According to USP <797>, which of the following statements is not true regarding the Responsibility of the Compounder?
   - a. Perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces.
   - b. Use laminar flow clean-air hoods, barrier
isolators, and other contamination control devices that are appropriate for the risk level.
c. Identify, weigh, and measure ingredients.
d. Reduce solid ingredients to the smallest reasonable particle size.

4. According to USP <797>, which statement regarding the Verification of Compounding Accuracy and Sterilization is true?
   a. Achieving and maintaining sterility and freedom from contamination is not the responsibility of the pharmacy technician.
b. It is the pharmacist’s responsibility to ensure that the sterile compound is free from microbial contamination.
c. Verification requires planned testing designed to demonstrate effectiveness of all procedures critical to the accuracy and purity of finished CSPs.
d. Packaged and labeled CSPs do not need to be visually inspected for physical integrity and expected appearance.

5. According to Appendix A of this textbook, how many separate process validations must be completed?
   a. 7
   b. 8
   c. 9
   d. 10

6. According to Appendix A of this textbook, what final score do you need to achieve in order to successfully pass process validation consistent with ACPE standards?
   a. 75%
   b. 90%
   c. 95%
   d. 100%

7. According to the section of USP <797> regarding Personnel Training and Evaluation in Aseptic Manipulation Skills, compounding personnel who fail written tests or whose media-fill test displays evidence of contamination shall be immediately:
   a. re-instructed and re-evaluated by expert compounding personnel to ensure correction of all deficiencies.
b. trained to comply with USP <797> standards.
c. relieved of sterile compounding duties until she or he passes the pharmacy certification exam.
d. re-evaluated by compounding personnel to ensure correction of deficiencies.

8. According to the section of USP <797> regarding Personnel Training and Evaluation in Aseptic Manipulation Skills, media-fill testing is used to
   a. train pharmacy technicians in sterile compounding.
b. test the skills of pharmacists.
c. assess the quality of the aseptic skill of compounding personnel.
d. all of the above

9. While processing an outpatient prescription, you notice that a patient who has refused counseling seems confused about his prescription and asks you questions about the medication dosage. Bearing in mind the responsibilities outlined in the Code of Ethics for Pharmacy Technicians, what is the best course of action?
   a. Answer the patient’s question regarding his medication.
b. Refer the patient to the patient information leaflet accompanying the prescription.
c. Refer the patient to the USP.
d. Ask the pharmacist to speak with the patient regarding his medication.

10. While working delivering drugs to the nursing unit, you notice that an unauthorized employee has gained access to the narcotic cabinet. You witness the employee placing several narcotic tablets into her pocket and walking away. Bearing in mind the responsibilities outlined in the Code of Ethics for Pharmacy Technicians, what is the best course of action?
    a. Do nothing. This did not happen in the pharmacy and therefore is not your problem.
b. Confront the employee and try to wrestle the narcotics away from her.
c. Return to the pharmacy and notify your supervisor prior to the end of your shift.
d. Immediately notify the unit supervisor and the pharmacy manager, who will contact the police. Write down any details of what you witnessed so that you may give a detailed account of the event.
Part 3: Assessment

MAKE CONNECTIONS

On a separate sheet of paper, write your answers to the following three questions, using complete sentences and making sure your answers are thorough and thoughtful. Note that the third question requires Internet access.

1. Considering what you’ve learned so far about sterile compounding and the effect(s) of aseptic technique on patient health and safety, what are the potential consequences of incorrect technique?

2. USP <797> guidelines require initial and annual training, which includes a written exam, process validation, and media-fill aseptic technique testing. Why is it important for the technician to undergo such rigorous testing? Why is it important to be re-tested annually?

3. Find and then explore the “.org” website for the USP. What is one advantage of having a hard copy of the USP on hand in the pharmacy? What is one advantage of accessing the website versus using the hard copy of the USP?

MEET THE CHALLENGE

Scenario  This “puzzling” activity helps you to become more familiar with some of the key terminology and abbreviations identified in this chapter.

Challenge  On your own, read the numbered key-term hints and fill in the associated numbered crossword squares with a boldfaced key term from this chapter. The key term should both suit the hint and fit in the squares. (Once you have completed this challenge, you might want to create additional crossword puzzles on your own, using the remaining chapter key terms and exchanging your blank puzzles and hints with classmates.)

ACROSS

1 A process validation tool
4 A skilled compounding artisan
6 The number of risk levels associated with sterile compounding
7 An organization that oversees pharmacy continuing education
10 An organization that supports health-system pharmacist
11 The number of procedural labs requiring process validation
12 An organization that sets commercial and industrial standards that often become law
14 Free from pathogenic contaminants
15 A practice that meets or exceeds the highest pharmacy standards
17 A type of certification exam for pharmacy technicians
18 Exploratory and procedural modules tested by process validation
19 The dilution, mixing, and injection of drugs using aseptic technique

DOWN

2 The topic of an APhA publication for pharmacy technicians
3 The person who prepares sterile compounds
5 Under the skin
8 A sterile injectable mediation that may be administered by the IV, IM, or Sub-Q routes
9 Injected into the space around the spine and brain
13 Injected into the vein
14 A type of aseptic technique testing kit
16 The art and science of preparing and dispensing medications

Exploring the Basics of Sterile Compounding
Additional Resources

Go to the Paradigm Internet Resources Center at www.emcp.net/sterilecomp to access live links related to these Chapter 1 topics:

- the ASHP guidelines
- the process for testing and national certification of pharmacy technicians
- pharmacy careers, advocacy, and professional support for hospital and health-system pharmacy personnel
- pharmacy careers, advocacy, and professional support for community and retail pharmacy personnel
- Federal laws and regulations on the manufacture and sale of drugs or other medical products
- preventing and reporting medication errors