Chapter 11

Aseptic Technique

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Introduction

Trained personnel using aseptic technique prepare all compounded sterile preparations (CSPs) under strict, sterile environmental conditions. According to the *United States Pharmacopeia* and *The National Formulary (USP–NF)*, *aseptic technique* is defined as a process by which separate, sterile components—such as drugs, containers, or closures—are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized via membrane filtration or autoclaving prior to combining.[1] Although various aseptic technique methods are used in many areas in healthcare, this chapter focuses on the application of aseptic technique in pharmacy practice.

Although the importance of sterility was first recognized in the late 1800s, the concept of aseptic technique was not described until years later.[2,3] The need to sterilize solutions and equipment became accepted in the 1920s and 1930s.[4-6] The development of sterile and pyrogen-free products and their applications continues today. In the late 1960s, improperly manufactured and compounded parenteral solutions caused a rash of complications in patients.[7-12] After these incidents, the National Coordinating Committee on Large Volume Parenterals was established and published recommendations for compounding sterile preparations by pharmacists and other health professionals.[13-19] A training manual for intravenous (IV) admixture personnel, largely intended for pharmacy technicians who prepare sterile products, was first published in 1972 and is now in its fifth edition.[20]

In response to the problems with CSPs, ASHP published a Technical Assistance Bulletin and the U.S. Pharmacopeial Convention (USP) published USP Chapter <1206> Sterile Products for Home Use to provide guidance on how to properly prepare sterile preparations; however, practitioners often did not follow these guidelines because they were not legally enforceable.[21,22] In 1938, the U.S. Congress passed the Federal Food, Drug and

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Cosmetic Act, which recognized all of the chapters with numbers lower than 1,000 in the *USP–NF* as legally enforceable standards and requirements for pharmacy practice.[23] The USP revised USP Chapter <1206> and published USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations on January 1, 1997, which emphasizes the need to maintain high standards for the quality and control of processes, components, environment, and properly trained and verified compounding personnel.[24] The chapter was revised again in 2004, which is the current official revision at the writing of this publication.[25] With the New England Compounding Center meningitis outbreak that caused 64 deaths and injured over 800 patients, USP Chapter <797> is undergoing another revision during the 2015–2020 USP cycle to further improve the quality of CSPs and patient safety.

To aid practitioners in meeting USP standards, ASHP published *The Basics of Aseptic Compounding Technique Video Training Program*.[26] This interactive resource—a DVD with companion workbook—emphasizes identification of product risk level, personnel qualifications, quality assurance practices, and controlled area requirements. ASHP also published *Getting Started in Aseptic Compounding*, a basic level training resource that includes a videotape/workbook and provides an introduction to the fundamentals of aseptic compounding.[27]

Requirements for Aseptic Technique

The quality of CSPs is only as good as the aseptic technique used. If a person is not properly trained on handwashing and garbing; correct use of equipment; working in proper clean environments; cleaning and disinfecting of surfaces, equipment, and supplies; sterilization methods; performing quality assurance; and aseptic manipulation skills, the sterility of CSPs may be compromised. Technique is a skill in the compounding of sterile preparations that is independent of equipment and environment. Good sterile compounding skills do not eliminate the need for the proper equipment and environment. Conversely, good equipment and the proper environment do not ensure high-quality sterile preparations if the person's aseptic technique is substandard.

The standards in USP Chapter <797> for traditional pharmacies and the current good manufacturing practices (cGMPs) for the U.S. Food and Drug Administration (FDA)–registered 503B outsourcing facilities both require that sterile compounding personnel receive specific expert training through audio-visual instructional resources, such as professional, hands-on training programs, and professional publications in both theoretical principles and the practical skills of aseptic technique. After personnel have been trained, they are required to demonstrate competency through written tests, visual evaluations by the compounding supervisors, and media fill testing to validate their aseptic technique. Demonstrating competency is done at routine intervals and on an ongoing basis. Chapter 30 addresses personnel training and competency.

Several chapters in this book cover in detail the requirements for aseptic technique: Chapter 9, Primary Engineering Controls; Chapter 10, Personnel Cleansing and Garbing; Chapter 27, Cleaning and Disinfecting; Chapter 28, Environmental Quality and Control; and Chapter 31, Policies, Procedures, and Quality Assurance Programs. Chapter 11 will provide information and instruction on the practical skills necessary for aseptic technique.

Equipment and Environment

Sterile compounding is done in a primary engineering control (PEC) that provides an International Organization for Standardization (ISO) Class 5 environment for the exposure of critical sites, with the exception of emergent medical situations that may require preparation at the point-of-care. Proper placement of the laminar airflow workbench (LAFW) is discussed in detail in Chapter 9. The most common PEC used for nonhazardous sterile compounding is the LAFW. For hazardous sterile compounding, a biological safety cabinet or a compounding aseptic containment isolator is used to provide an ISO Class 5 environment and to protect the compounder from exposure to hazardous substances. These PECs are discussed in detail in Chapter 12, Handling and Compounding Hazardous Drugs.