Course Title: Pharmacy Compounding and Sterile Preparations

Course Description: The Texas Administrative Code, Title 22, Part 15, Chapter 291, Subchapter A, Rule §291.26 requires that all pharmacy technicians preparing sterile pharmaceuticals shall receive didactic, experiential training, and competency evaluation by a pharmacist that has completed a recognized course in an accredited college of pharmacy or a course sponsored by an Accreditation Council for Pharmacy Education (ACPE) approved provider which provides a minimum of 40 hours of total instruction including 20 hours of labs.

This comprehensive 50 hour program is sponsored by the ACPE and meets the above standards. Students will explore all types of parenteral medications – the terminology and equipment commonly associated with them, as well as the various methods used in their preparation and the program will prepare students to work with Sterile Compounding, IV Admixtures and Aseptic preparation. The program will also include key review and extensive classroom demonstrations and labs covering required subjects including: aseptic/sterile techniques; IV Admixtures; critical area contamination factors; environmental monitoring; facilities; equipment and supplies; sterile pharmaceutical calculations and terminology; sterile pharmaceutical compounding documentation; quality assurance procedures; aseptic preparation procedures including proper gowning and gloving technique; handling of cytotoxic and hazardous drugs; general conduct in the controlled area; as well as other important topics, demonstrations and labs.

Course Prerequisite(s): Must be a Registered Pharmacist, Certified Pharmacy Technician, or must have recently completed a Pharmacy Technician course

Course Objectives:
- List and describe a broad-base of regulatory activities required when compounding sterile preparations
- Define aseptic compounding and explain the need for sterile products
- Explain why it is important that the parenteral administration routes must be sterile or prepared aseptically
- Distinguish and explain the different forms of parenteral administration
- Explain and demonstrate how laminar flow hoods contribute to infection control
- Show calculations related to products prepared using aseptic technique
- Calculate the quantity of active ingredient needed for each preparation
- Calculate the volume of active ingredient to add to an IV mixture
- Calculate the volume of electrolytes to add to a TPN
- Determine the rate of flow for IV meds
- Explain the cautions associated with microbial contamination
- Understand the pH range and why it is important
- Understand the concepts of compatibility and stability
- Explain the difference between tonicity, osmolarity and osmolality
- Describe and perform how to prepare vials, bags, and ampules before placing them in the airflow hood
• Explain and perform how to manipulate supplies such as needles, filters, and syringes
• Describe and perform reconstituting a sterile product
• Explain why a patient receives TPN and list the additives used in making a TPN
• Describe and perform the admixture of a TPN
• Discuss and perform safety procedures for handling chemotherapy agents
• List hazards involved in preparing chemo agents
• Describe how to clean a chemo spill
• Describe packaging devices and materials used in the preparation of sterile dosage forms
• Describe the history of compounding and the implications of USP Chapter <797>
• Perform Non-Hazardous Drug Compounding Personnel cleansing, garbing, and material handling
• Execute Hazardous Drug Compounding Personnel cleansing, garbing, and material handling
• Identify the process of determining compounded sterile preparation (CSP) beyond use dating
• Describe in detail perform the steps and stages of personal preparation when entering into an anteroom, and then into a clean room; hand washing, garbing, gloving in the anteroom and moving, and body positioning
• Complete labeling, packaging, and handling procedures for receiving products, delivery of products, and inventory control
• Present material handling procedures including the preparation and disposal of hazardous drugs
• List the physical and chemical active agent/excipient properties applicable to compounded sterile preparations
• Identify parameters surrounding particulate limits with respect to number and size for compounded sterile preparations

Textbook(s): (Provided)
1. “Compounding Sterile Preparations”, second edition, E. Clyde Buchanan, Phyllip J. Schneider (The American Society of Health-System Pharmacists (the “PT Sterile Prep Text Book”)
   a. Section #1 & #2 – Pages #1 to #252
   b. Appendixes A through H

Lesson Plan

Session 1: Guidelines for Sterile Preparations, Sterile Preparation Formulation, and Equipment for Sterile Compounding
Session 2: Isolators, Personal Behavior and Garb, and Aseptic Technique
Session 3: Handling, Compounding and Disposal of Cytotoxic and Hazardous Drugs, Factors Influencing Beyond Use Dating of Compounded Sterile Preparations, and Labeling Sterile Preparations
Session 4: ASHP Guidelines for Quality Assurance for Pharmacy - Prepared Sterile Products
   Perform process validation for Lab #1 – Aseptic Hand Washing Technique and Lab #2 – Personal Garb
Session 5: ASHP Guidelines on Pharmacy Prepared Ophthalmic Products
Perform process validation for Lab #3 – Horizontal Laminar Airflow Hood and Lab #4 – Vertical Laminar Airflow Hood

Session 6: Documentation of Compounded Sterile Preparations, Handling of Sterile Commercial Products, Preparation within a Pharmacy and Maintaining the Integrity of Compounded Sterile Preparations Outside the Pharmacy

Session 7: Compounding and Sterilization of Batch Preparations and Batch Compounding Documentation

Session 8: Pharmacists Education, Pharmacy Technician Education, Certification, and Training, and Sterile Preparation Facilities and Equipment

Perform process validation for Lab #5 – Ampule Preparation and Lab #6 – TPN Preparation

Session 10: ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs
Perform process validation for Lab #7 – Ophthalmic Preparations and Lab #8 – Sterile Product Label Preparations

Session 11: Environmental Monitoring, Dealing with Latex Allergy

Session 12: End-Preparation Evaluation, Policies and Procedures for Compounding Sterile Preparations, and Outsourcing the Compounding of Sterile Preparations

Session 13: Hospital Pharmacies – Status as Drug Manufacturer and Compliance Policy Guide
Perform process validation for Lab #9 – Ampule Preparation (Hazardous Drugs)

Session #14 Model Rules for Sterile Pharmaceuticals, Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Healthcare Settings
Perform process validation for Lab #10 – Vial Preparation (Hazardous Drugs)

Session #15 Final Examination