STERILE PRODUCTS
Course Syllabus

Course Number: APT-0122  
OHLAP Credit: No
OCAS Code: None
Course Length: 45 Hours
Career Cluster: Health Science
Career Pathway: Therapeutic Service
Career Major(s): Advanced Pharmacy Technician

Pre-requisite(s): Students will learn the theory and principal aspects of a pharmacy sterile program. Terminology, techniques, quality control and quality assurance are covered. Students will perform all pharmaceutical calculations for compounding sterile products.

Textbooks:
- Pharmacy Calculations for Technicians 5th Edition, text with Study Partner CD
- Certification Exam Review 3rd Edition, text with Study Partner CD
- Pharmacy Practice for Technicians 5th Edition, text with Study Partner CD
- Pharmacy Labs for Technicians, Second Edition, text with NRx Simulation CD
- Blackboard

Course Objectives:

A. Introduction to Sterile Products
1. Define aseptic compounding and explain the need for sterile products.
2. Distinguish between inhalants, enterals, topicals, ophthalmics, otics and parenterals as dosage forms used in sterile products.
3. Explain why it is important the parenterals administration route must be sterile or prepared aseptically.
4. Distinguish and explain the different forms of parenteral administration.
5. Determine which types of parenteral administration must be preservative-free.

B. Facilities, Garb, and Equipment
1. Explain how laminar flow biological safety cabinets contribute in infection control.
2. Describe the difference among class 100, 1000, and 10,000 clean rooms.
3. Explain the importance of aseptic technique in compounding.
4. Explain the reason for each step in the proper procedure for cleaning a laminar flow biological safety cabinet.
5. Describe the proper protective dress required in a clean room.

C. Aseptic Calculations
1. Show calculations related to products prepared using aseptic technique.
2. Calculate the quantity of active ingredient needed for each preparation.
3. Calculate the volume of active ingredient to add to an IV admixture.
4. Calculate the volume of electrolytes to add to a TPN.  
5. Discuss and calculate dilution technique.

D. **Properties of Sterile Products**
1. Explain the cautions associated with microbial contamination.  
2. Understand the pH range and why it is important.  
3. Understand the concepts of compatibility and stability.  
4. Explain the difference between tonicity, osmolarity and osmolality.  
5. Know how to calculate the osmolarity of an IV solution.

E. **Aseptic Technique**
1. Define aseptic compounding and explain the need for sterile products.  
2. Distinguish between inhalants, enterals, topicals, ophthalmics, otics, and arenterals as dosage forms used in sterile products.  
3. Explain why it is important that the parenterals administration route must be sterile or prepared aseptically.  
4. Distinguish and explain the different forms of parenteral administration.  
5. Determine which types of parenteral administration must be preservative-free.

F. **Sterile Product Preparations**
1. List and describe the different types of sterile products.  
2. Know the different used for large-volume and small-volume IV bags.  
3. Understand the concept of pediatric dosing and realize why sterile products prepared for this type of patient are different from those for adults.  
4. List some specialty protein-based sterile products.

G. **Total Parenteral Nutrition**
1. Explain why a patient receives a TPN.  
2. List the additives used in making TPN.  
3. Explain why the ingredients are necessary in a TPN.  
4. Describe how to admix a TPN.  
5. Discuss automated mixing equipment.

H. **Chemotherapy**
1. Describe what happens with cancer and cells.  
2. Explain how cytotoxic agents are used to treat cancer.  
3. Explain safety procedures of handling chemotherapy agents.  
4. Describe the types of biological safety cabinets.  
5. Discuss appropriate procedures for preparing chemotherapy agents.  
6. List the hazards involved with preparing chemotherapy agents.  
7. Describe how to clean a chemotherapy spill.

I. **Quality Control and Assurance**
1. Explain the necessity of quality control.  
2. State task that require quality assurance procedures.  
3. Help the pharmacist ensure the quality of all pharmaceutical services.  
4. List the principles of quality assurance to all pharmacy activities.  
5. Discuss the implications of USP Chapter 797.  
6. Compare the various risk levels for differing compounded sterile preparations and the quality-assurance requirements of each.

J. **Process Validation**
1. Demonstrate the following skills in the pharmacy setting:  
   a. Aseptic Hand Washing  
   b. Horizontal Laminar Airflow Hood  
   c. Ampule Preparation
d. TPN Preparation

e. Ampule Preparation- Hazardous Drugs

f. Vial Preparation-Hazardous Drugs

g. Sterile Ophthalmic Solution Preparation

h. Sterile Product Label Preparation

i. Vertical Laminar Airflow Hood

1 ODCTE Objective
All unmarked objectives are TTC instructor developed.

Teaching Methods: The class will primarily be taught by the lecture and demonstration method and supported by various media materials to address various learning styles. There will be question and answer sessions over material covered in lecture and media presentations. Supervised lab time is provided for students to complete required projects.

Grading Procedures: 1. Students are graded on theory and lab practice and performance.

2. Each course must be passed with seventy (70%) percent or better.

3. Grading scale: A=90-100%, B=80-89%, C=70-79%, D=60-69%, F=50-59%.

4. Career Major grades established during coursework are a major criteria in successfully obtaining certification.

Description of Classroom, Laboratories, and Equipment: Tulsa Technology Center campuses are owned and operated by Tulsa Technology Center School District No. 18. All programs provide students the opportunity to work with professionally certified instructors in modern, well-equipped facilities.

Available Certifications/College Credit The student may be eligible to take state, national or industry exam after completion of the program. College credit may be issued from Oklahoma State University-Okmulgee or Tulsa Community College. See program counselor for additional information.

College Credit Eligibility: The student must maintain a grade point average of 2.0 or better.