

# PHA5104 Sterile Compounding

Spring 2021

1 Credit Hour – [A-E Grading]

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*The purpose of this course is to introduce the student to sterile compounding in pharmacy practice. The content examines the current standards and best practices for preparing a sterile compound. Topics include pertinent information from USP Chapter 797, calculations, microbiological considerations, selection of sterile compounding equipment, engineering controls, aseptic technique, stability and compatibility considerations, quality assurance and product verification. Special topics include preparation of total parenteral nutrition, hazardous preparations, and special needs of infants and children. This course prepares the student for developing skills related to sterile compounding during the professional practice skills laboratory courses and sterile compounding during the Hospital Introductory Pharmacy Practice Experience (HIPPE). This will enable the student to prepare sterile compounds as a pharmacist.*

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## Teaching Partnership Leader

William Cary Mobley, R.Ph., Ph.D.

- Email: [mobley@cop.ufl.edu](mailto:mobley@cop.ufl.edu)
- Office: HPNP 1315/GNV
- Phone: 352-273-6282
- Office Hours: Please see Canvas course site for posted office hours.

See Appendix A. for Course Directory of Faculty and Staff Contact Information.

## Entrustable Professional Activities

This course will prepare you to perform the following activities that which the public entrusts a Pharmacist to perform:

1. EPA E4. Safely and accurately dispense medications within a medication use system including supervision of pharmacy technicians.

## Course-Level Objectives

Upon completion of this course, the student will be able to:

1. List the standards and regulations for sterile compounding.
2. List the roles and responsibilities of personnel involved in sterile compounding.
3. Describe supplies and equipment used to safely compound and administer compounded sterile preparations.
4. Perform calculations commonly utilized for the compounding and administration of compounded sterile products.

5. Describe important concepts related to microbiological contamination of compounded sterile preparations including modes, influencing factors, consequences, risk levels, and prevention.
6. Describe the different types of primary and secondary engineering controls that are important for sterile compounding.
7. Outline steps of aseptic technique and specific compounding manipulations.
8. Describe labeling requirements for compounded sterile preparations.
9. Describe guidelines and engineering controls important for the proper handling of hazardous agents used in sterile compounding.
10. Describe concepts of quality for compounded sterile preparations.
11. Describe methods of final product verification of compounded sterile preparations.
12. List factors that influence the compatibility and stability of parenteral preparations.
13. Describe Beyond Use Dates (BUDs) and how to assign them using available resources.
14. Describe essential concepts and methods of evaluating the stability and compatibility.
15. Describe essential concepts and techniques for the preparation of parenteral nutrition preparations.
16. Describe special considerations for parenteral drug therapy in infants and children.

## Course Pre-requisites

1. Completion of all Year 1 Pharm.D. program coursework including milestones.

## Course Co-requisites

1. PHA5784 Patient Care IV: GI/Renal
2. PHA5164 Professional Practice Skills Laboratory IV

## Course Outline

Please routinely check your campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/times, deadlines, and room changes.

<i>Date</i>	<i>Mod#</i>	<i>Unit Topic</i>	<i>Contact Hours</i>	<i>Faculty Author</i>	<i>Learning Objectives Covered</i>
1/6/21	1	Module 1: Introduction to Sterile Compounding	2.5hr	Campbell, Mobley	1-4
	1.1	Watch: Introduction to Parenteral Preparations, Supplies, and Equipment	0.75hr	Campbell	
	1.2	Watch: Calculations for Parenterals I	1hr	Mobley	
	1.3	Watch: Calculations for Parenterals II	0.75hr	Mobley	

<i>Date</i>	<i>Mod#</i>	<i>Unit Topic</i>	<i>Contact Hours</i>	<i>Faculty Author</i>	<i>Learning Objectives Covered</i>
	2	Module 2: Fundamental Concepts – Microbiological Considerations	2.5hr	Garcia-Carranza, Tahiliani	5, 6
	2.1	Watch: Microbiological Considerations in Parenteral Compounding	0.75hr	Garcia-Carranza	
	2.2	Watch: Primary and Secondary Engineering Controls	0.75hr	Tahiliani	
		Read: USP 797 (based off of the numbers on the top of the page): <ul style="list-style-type: none"> <li>• Page 8: Hazardous Drugs as CSP</li> <li>• Pages 11-14 Environmental Quality &amp; Control- Placement of Primary Engineering Controls</li> <li>• Page 17-19: Cleaning &amp; Disinfecting the Compounding Area and Personnel Cleansing &amp; Garbing</li> </ul> USP 800: <ul style="list-style-type: none"> <li>• Section 5 pages 4-7</li> <li>• Section 7 pages 8-9</li> </ul>	1.0hr		
<b>1/7/21 11:59 PM</b>	1.1 and 2.1	Out-of-Class Quiz 1			
<b>1/8/21 1:55-3:50 PM</b>	2.2 (incl. Reading)	Active Learning Session 1 - Hybrid In-Class Quiz 1	2.0hr	Tahiliani, Mobley,	5,6
	3	Module 3: Compounding Sterile Preparations	1.75hr	McKean, Esperon	7-9
	3.1	Watch: Aseptic Technique and Compounding Manipulations	1.0hr	McKean	

<i>Date</i>	<i>Mod#</i>	<i>Unit Topic</i>	<i>Contact Hours</i>	<i>Faculty Author</i>	<i>Learning Objectives Covered</i>
	3.2	Watch: Preparation of Hazardous Drugs for Parenteral Use	0.75hr	Esperon	
	4	Module 4: Quality in Sterile Compound and Final Product Verification	1.75hr	Tucker	10, 11
	4.1	Watch: Quality in Sterile Compounding and Final Product Verification	1.0hr	Tucker	
		Read: Quality in Sterile Compounding and Final Product Verification	0.75hr	Tucker	
<b>1/12/21 11:59 PM</b>	3 and 4 (incl. Reading)	Out-of-Class Quiz 2			
<b>1/13/21 8:30-10:25 AM</b>	1 and 4	Active Learning Session 2 - Hybrid In-Class Quiz 2 – Calculations	2.0hr	Schmittgen, Vandervoort, Mobley,	4, 8, 11
	5	Module 5: Stability and Compatibility of Sterile Preparations	1.5hr	Giaquinta, Schmittgen	12-14
	5.1	Watch: Principles of Compatibility and Stability	0.75hr	Giaquinta	
	5.2	Watch: How to Evaluate Literature – Principles of Compatibility and Stability	0.75hr	Schmittgen	
	6	Module 6: Specialties within Sterile Compounding	1.5hr	Scott, Hernandez	15, 16
	6.1	Watch: Multiple Product Preparations for Parenteral Nutrition	0.75hr	Scott	
	6.2	Watch: Considerations for Intravenous Drug Therapy in Infants and Children	0.75hr	Hernandez	
<b>1/14/21 11:59 PM</b>	5 and 6	Out-of-Class Quiz 3			

<i>Date</i>	<i>Mod#</i>	<i>Unit Topic</i>	<i>Contact Hours</i>	<i>Faculty Author</i>	<i>Learning Objectives Covered</i>
<b>1/15/21 8:30-10:30 AM</b>	1-6	Final Exam	2.0hr		1-16
		Total Contact Hours in Course:	15.5hr		

## Required Textbooks/Readings

Ochoa PS and Vega JA. *Concepts in Sterile Preparations and Aseptic Technique*. Jones & Bartlett Learning. Burlington, MA, 2015. ISBN-13: 9781284035728

- Not Available via HSC Library

## Suggested Textbooks/Readings

Ochoa PS and Vega JA. *Concepts in Sterile Preparations and Aseptic Technique*. Jones & Bartlett Learning. Burlington, MA, 2015. ISBN-13: 9781284035728

- Not Available via HSC Library

0 suggested readings will be posted in Canvas.

## Other Required Learning Resources

Non-programmable calculators are required for this course.

## Materials & Supplies Fees

None

## Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.

The Canvas© gradebook will be set-up using the percentages below to compute the grade.

<b>Assessment Item</b>	<b>Grade Percentage</b>
<b>Out-of-Class Quizzes [3]</b>	6%
<b>In-Class Quizzes [2]</b>	20%
<b>Active Learning Documentation</b>	10%
<b>Final Exam</b>	64%
<b>Total</b>	100%

Table 1. Grading Scale

**Rounding of grades:**

Final grades in Canvas will be rounded to the 2<sup>nd</sup> decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and NO EXCEPTIONS will be made in situations where a student's grade is "close."

**Educational Technology Use**

The following technology below will be used during the course and the student must have the appropriate technology and software.

1. ExamSoft™ Testing Platform
2. Canvas™ Learning Management System

For technical support, navigate to [Educational Technology and IT Support Contact Information](#) at this URL:

<http://curriculum.pharmacy.ufl.edu/current-students/technical-help/>

**Pharm.D. Course Policies**

The Policies in the following link apply to this course. Review the [Pharm.D. Course Policies](#) carefully, at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/course-policies/>

Percentage Range	Letter Grade
92.50-100%	A
89.50-92.49%	A-
86.50-89.49%	B+
82.50-86.49%	B
79.50-82.49%	B-
76.50-79.49%	C+
72.50-76.49%	C
69.50-72.49%	C-
66.50-69.49%	D+
62.50-66.49%	D
59.50-62.49%	D-
< 59.50%	E

# Appendix A. Course Directory

## Teaching Partnership Leader/Course Director:

William Cary Mobley, R.Ph., Ph.D.

Email: [mobley@cop.ufl.edu](mailto:mobley@cop.ufl.edu)

Office: HPNP 1335/GNV

Phone: 352-273-6282

Office Hours: Please see Canvas course site for posted office hours.

### Questions to Ask:

- Questions about grades
- Concerns about performance
- Guidance when there are performance problems (failing grades)
- General questions about content

## Academic Coordinator:

Name: Misti Merrill

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Office: HPNP 4312/GNV

Phone: 352-273-6523

Office Hours: By appointment ONLY.

### Questions to Ask:

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence requests (Only the Academic Coordinator handles absence requests)
- Questions about dates, deadlines, meeting place
- Availability of handouts and other course materials
- Assignment directions
- Questions about grade entries gradebook (missing grades, wrong grade)
- Assistance with ExamSoft® (Distant campus students may contact Education Coordinator for use of SofTest and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.)

## Other Teaching Partnership Faculty Members:

Courtney Campbell, Pharm.D.

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