PHA5104 Sterile Compounding

Spring 2018

1 Credit Hour – [A-E Grading]

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.

Teaching Partnership Leader

William Cary Mobley, R.Ph., Ph.D.
- Email: mobley@cop.ufl.edu
- Office: HPNP 1315/GNV
- Phone: 352-273-6282
- Office Hours: By appointment ONLY.

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 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.
15. Describe essential concepts and techniques for the preparation of parenteral nutrition preparations.

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.

<table>
<thead>
<tr>
<th>Date Recommended Dates for Independent Study</th>
<th>Mod#</th>
<th>Unit Topic</th>
<th>Contact Hours [hr.]a</th>
<th>Faculty Author</th>
<th>Learning Objectives Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>Module 1: Introduction to Sterile Compounding</td>
<td>2.5hr</td>
<td>Voils, Schentrup</td>
<td>1-4</td>
</tr>
<tr>
<td>1/4/18</td>
<td>1.1</td>
<td>Watch: Introduction to Parenteral Preparations, Supplies, and Equipment</td>
<td>1.0hr</td>
<td>Voils</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Mod#</td>
<td>Unit Topic</td>
<td>Contact Hours [hr.]a</td>
<td>Faculty Author</td>
<td>Learning Objectives Covered</td>
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<tr>
<td>1/4/18</td>
<td>1.2</td>
<td>Watch: Calculations for Parenterals I</td>
<td>0.75hr</td>
<td>Schentrup</td>
<td></td>
</tr>
<tr>
<td>1/4/18</td>
<td>1.3</td>
<td>Watch: Calculations for Parenterals II</td>
<td>0.75hr</td>
<td>Schentrup</td>
<td></td>
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<tr>
<td>2</td>
<td>Module 2: Fundamental Concepts – Microbiological Considerations</td>
<td>2.5hr</td>
<td>Hoggard</td>
<td>5, 6</td>
<td></td>
</tr>
<tr>
<td>1/5/18</td>
<td>2.1</td>
<td>Watch: Microbiological Considerations in Parenteral Compounding</td>
<td>0.75hr</td>
<td>Hoggard</td>
<td></td>
</tr>
<tr>
<td>1/5/18</td>
<td>2.2</td>
<td>Watch: Primary and Secondary Engineering Controls</td>
<td>0.75hr</td>
<td>Hoggard</td>
<td></td>
</tr>
<tr>
<td>1/5/18</td>
<td>0.75hr</td>
<td>1.0hr</td>
<td></td>
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<td></td>
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<tr>
<td>2</td>
<td>Module 3: Compounding Sterile Preparations</td>
<td>3.75hr</td>
<td>Voils, Esperon</td>
<td>7-9</td>
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<tr>
<td>1/6/18</td>
<td>3.1</td>
<td>Watch: Aseptic Technique and Compounding Manipulations</td>
<td>1.0hr</td>
<td>Voils</td>
<td></td>
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<tr>
<td>1/6/18</td>
<td>3.2</td>
<td>Watch: Preparation of Hazardous Drugs for Parenteral Use</td>
<td>0.75hr</td>
<td>Esperon</td>
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<tr>
<td>1/8/18 8:30-10:25am All Campuses</td>
<td>1-3</td>
<td>Active Learning Session 1</td>
<td>2.0hr</td>
<td>Mobley, Hoggard</td>
<td>1-9</td>
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<tr>
<td>4</td>
<td>Module 4: Quality in Sterile Compound and Final Product Verification</td>
<td>1.75hr</td>
<td>Ebied</td>
<td>10, 11</td>
<td></td>
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<tr>
<td>1/8/17</td>
<td>4.1</td>
<td>Watch: Quality in Sterile Compounding and Final Product Verification</td>
<td>1.0hr</td>
<td>Ebied</td>
<td></td>
</tr>
<tr>
<td>1/8/17</td>
<td>0.75hr</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5</td>
<td>Module 5: Stability and Compatibility of Sterile Preparations</td>
<td>1.5hr</td>
<td>Giaquinta, Hatton</td>
<td>12-14</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Mod#</td>
<td>Unit Topic</td>
<td>Contact Hours [hr.]</td>
<td>Faculty Author</td>
<td>Learning Objectives Covered</td>
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<tr>
<td>1/8/17</td>
<td>5.1</td>
<td>Watch: Principles of Compatibility and Stability</td>
<td>0.75hr</td>
<td>Giaquinta</td>
<td></td>
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<tr>
<td>1/8/17</td>
<td>5.2</td>
<td>Watch: How to Evaluate Literature – Principles of Compatibility and Stability</td>
<td>0.75hr</td>
<td>Hatton</td>
<td></td>
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<td>1/9/17</td>
<td>6.1</td>
<td>Watch: Multiple Product Preparations for Parenteral Nutrition</td>
<td>0.75hr</td>
<td>Kamel</td>
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<td>1/9/17</td>
<td>6.2</td>
<td>Watch: Considerations for Intravenous Drug Therapy in Infants and Children</td>
<td>0.75hr</td>
<td>Hernandez</td>
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<td>1/10/18</td>
<td>4-6</td>
<td>Active Learning Session 2</td>
<td>2.0hr</td>
<td>Mobley, Ebied</td>
<td>10-16</td>
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<td>1/12/18</td>
<td>1-6</td>
<td>Final Exam</td>
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<td>1-16</td>
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**Total Contact Hours in Course:** 15.5hr

### Required Textbooks/Readings


- Not Available via HSC Library

Use [UF VPN to access UF Libraries Resources](http://www.library.health.ufl.edu/) when off-campus. The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the [HSC Library Website](http://www.library.health.ufl.edu/) at this URL: [http://www.library.health.ufl.edu/](http://www.library.health.ufl.edu/)

### Suggested Textbooks/Readings

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.]

<table>
<thead>
<tr>
<th>Assessment Item</th>
<th>Grade Percentage</th>
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<tbody>
<tr>
<td>Out-of-Class Quizzes [3]</td>
<td>6%</td>
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<tr>
<td>In-Class Quizzes [2]</td>
<td>20%</td>
</tr>
<tr>
<td>Active Learning Documentation</td>
<td>10%</td>
</tr>
<tr>
<td>Final Exam</td>
<td>64%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Table 1. Grading Scale

Rounding of grades:

Final grades in Canvas will be rounded to the 2nd 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/
Appendix A. Course Directory

Teaching Partnership Leader/Course Director:

William Cary Mobley, R.Ph., Ph.D.
Email: mobley@cop.ufl.edu
Office: HPNP 1335/GNV
Phone: 352-273-6282
Office Hours: By appointment ONLY.

Questions to Ask:

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

Academic Coordinator:

Name: Holly Fremen
Email: holly.fremen@cop.ufl.edu
Office: HPNP 4312/GNV
Phone: 352-294-8677
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:

Alissa Voils, Pharm.D., MSHA
Email: voilsa@shands.ufl.edu
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