Best Practices and Compliance with USP 795 for Nonsterile Compounding eCourse Curriculum
11 lessons with 11 hours of CE
eLesson Learning and Performance Objectives

Introduction to Nonsterile Pharmacy Compounding (1 hour)
0761-9999-19-222-H07-P
0761-9999-19-222-H07-T
- List elements pertaining to nonsterile pharmacy compounding.
- Explain the fundamental principles of USP 795.
- Describe the industry standards for USP 795.
- Define the basic terms that apply to nonsterile pharmacy compounding.
- Recall basic terminology related to nonsterile pharmacy compounding.

Mathematics Review and Pharmaceutical Excipients (1 hour)
0761-9999-19-223-H07-P
0761-9999-19-223-H07-T
- Identify the correct formulas required to complete nonsterile pharmaceutical calculations.
- Correctly solve mathematical calculations/equations that relate to nonsterile compounding.
- Discuss pharmaceutical excipients used in nonsterile compounding.

Responsibilities of the Compounder and Compounding Facility Requirements (1 hour)
0761-9999-19-224-H07-P
0761-9999-19-224-H07-T
- Identify the responsibilities of the compounder and the designated person in USP 795.
- List the personnel qualifications identified by USP 795.
- Practice good hand hygiene, appropriate garbing, and use of PPE.
- Describe USP 795 requirements for nonsterile compounding facilities.
- Properly list requirements for a clean compounding environment.
- Explain basic ergonomics and how they apply to nonsterile compounding facilities and compounders.
- Discuss requirements, resources, and guidelines for preparing hazardous compounded nonsterile preparations (CNSPs).

Component Selection, Receipt, Handling, and Storage (1 hour)
0761-9999-19-225-H07-P
0761-9999-19-225-H07-T
- Define the requirements for component selection in USP 795.
- Describe the storage requirements per USP 795.
- Outline proper component-handling activities.
- Demonstrate the ability to read and understand a certificate of analysis (COA).
- Describe the requirements for receipt of component(s) in USP 795.
Nonsterile Compounding Equipment (1 hour)
0761-9999-19-226-H07-P
0761-9999-19-226-H07-T
- Define the requirements for the use of compounding equipment and USP 795.
- List the types of equipment and their basic functions used in nonsterile compounding.
- Evaluate the cleaning schedule for nonsterile compounding equipment.

Nonsterile Compounding Process (1 hour)
0761-9999-19-227-H07-P
0761-9999-19-227-H07-T
- Identify the different methods used to compound nonsterile preparations.
- Outline proper compounding techniques for each nonsterile dosage form.

Beyond-Use Dating (BUD) and Chemical Stability of Nonsterile Compounds (1 hour)
0761-9999-19-228-H07-P
0761-9999-19-228-H07-T
- Define basic terminology associated with beyond-use dates.
- Review USP Chapter 1112 and how it affects BUDs for CNSPs.
- Define stability considerations.
- Assign BUDs to nonsterile pharmaceutical compounds consistent with USP 795.

Packaging and Documentation of Nonsterile Formulations (1 hour)
0761-9999-19-229-H07-P
0761-9999-19-229-H07-T
- List the requirements for packaging and drug preparation containers.
- Describe the labeling process and requirements.
- Identify the elements required for proper development of master formulation records and compounding records.
- Implement meaningful use of safety data sheets (SDS).
- Develop comprehensive, detailed standard operating procedures (SOPs) for nonsterile compounding practice.
- Review the transportation guidelines of compounded nonsterile preparations (CNSPs) in USP 795.

Quality Control and Release Testing in a Nonsterile Compounding Practice (1 hour)
0761-9999-19-230-H07-P
0761-9999-19-230-H07-T
- List the methods for release inspection required in USP 795.
- Describe different quality systems in USP 795.
- Explain how to handle product complaints and adverse event reporting.
- Define best practices for patient counseling of CNSPs.
Staff Training and Competency for Nonsterile Compounding (1 hour)
0761-9999-19-231-H07-P
0761-9999-19-231-H07-T

• Describe required staff training for personnel performing nonsterile compounding with USP 795.
• Implement a program that ensures effective initial and ongoing training.
• Review basic requirements for the training documentation in USP 795.
• Develop and implement procedural training and evaluation documents with USP 795.

Nonsterile Compounding for Animals (1 hour)
0761-9999-19-232-H07-P
0761-9999-19-232-H07-T

• Define the requirements for animal compounding in USP 795.
• Discuss the laws, regulatory requirements, and conundrums associated with compounding for animals.
• Review responsibilities of the veterinarian.