Sterile Compounding Boot Camp® Live Training Series
Best Practices for Nonsterile to Sterile Compounding

Day 1

Time	Description of Session	Learning Objectives (for CE Sessions)
8:00-8:30 am	*Housekeeping, Welcome and Introductions*	
8:30-9:45 am	What's all the Fuss about Nonsterile to Sterile Compounding?	• Define nonsterile to sterile compounding as it relates to your practice. • Assign the proper BUD based on the current version of USP 797 (2008) as well as prepare for the changes based on the USP 797 (2019). • Implement processes and work practices necessary to mitigate the increased compounding risks associated with nonsterile to sterile compounding.
9:45-10:00 am	*Break*	
10:00-11:30 am	Getting What you Need Ready to Go: Physical Plant, Components, Supplies, Equipment and Vendors	• List the best practice recommendations for physical plant, components, supplies, equipment and vendors required for nonsterile to sterile compounding. • Discuss the difference between master formulation records and compounding records. • Formulate quality agreements with any vendors of services that will be outsourced. • Evaluate the different filters and equipment available and choose the proper materials to suit your compounding practice. • Discuss proper methods of sterilizing nonsterile packaging.
11:30-12:30 pm	Two Simultaneous Interactive Exercises (11:30-12:00 and 12:00-12:30)	
	Master Formulation and Batch Records (Group 1 then Group 2)	• Distinguish between a variety of master formulation records and compounding records to identify those that include all the elements required in the USP 797 (2019).
	Selecting and API (Group 2 then Group 1)	• Distinguish between a variety of certificates of analysis and select those that represent appropriate API to use to compound sterile preparations.
12:30-1:15 pm	*Lunch*	

Day 1 (continued)

Time	Description of Session	Learning Objectives (for CE Sessions)
1:15-2:45 pm	Methods of Sterilization: Filtration, Dry Heat and Moist Heat	• Contrast and compare sterility assurance outcomes of terminal sterilization versus sterilization by filtration. • Differentiate between the types of sterilization (sterilization by filtration, steam sterilization and dry heat sterilization) and when each is appropriate. • Describe critical operational work practices of each type of sterilization.
2:45-3:00 pm	*Break*	
3:00-4:00 pm	What is Process Verification and Do We Really Need It?	• Identify the differences between validation and verification and apply these activities to nonsterile to sterile compounding. • List the different aspects of equipment qualification and understand how these relate to sterilizations methods, including dry heat ovens and autoclaves. • Recognize the difference between a positive and negative biological indicator.
4:00-5:00 pm	Interactive Exercise: Performing Temperature Mapping and Designing load Characteristics	• Observe autoclave temperature mapping. • List best practice recommendations for temperature mapping frequency. • Develop load criteria documents for the loads that are autoclaved at your facility.
5:00-5:15 pm	*Summary*	

Day 2

Time	Description of Session	Learning Objectives (for CE Sessions)
8:00-8:15 am	*Welcome and Introduction to the Day*	
8:15-9:45 am	Quality Release Checks and Tests	• Recognize when a filter integrity test is required and the critical elements of documentation. • Describe a compliant USP 71 sterility test and identify the limitations of the test. • Compare and contrast commercial “sterility testing” products and determine if they meet the requirements of USP 71. • Define bacterial endotoxin testing, when it is required and why it is an essential part of ensuring patient safety. • List the testing requirements based on Table 11 in USP 797 (2019).
9:45-10:00 am	*Break*	

Day 2 (continued)

Time	Description of Session	Learning Objectives (for CE Sessions)
10:00-11:30 am	3 Simultaneous Interactive Exercises (Pick 2 to attend prior to training) 1st session 10:00-10:45 and 2nd session 10:45-11:30 am	
	Bubble Point Demonstration and Practice	• List the supplies and equipment needed for the bubble point test. • Perform filter integrity testing by observing and practice a bubble point test. • Describe the characteristics of a passing versus failing bubble point. • Describe the actions to be taken in the event of a bubble point failure. • List the required elements of documentation.
	Sterility Testing: What to send, how it's done and reviewing reports of results	• List the supplies, equipment and controlled environment needed to perform USP 71 testing. • Observe a video of a USP 71 test. • Determine how many units and how much from each unit must be tested based on real life examples. • Review sterility test reports and identify required information.
	Bacterial Endotoxin Testing using Kinetic/Chromogenic Equipment: Overview and Demonstration	• Observe bacterial endotoxin testing performed on one type of commercial system that uses kinetic/chromogenic methods. • Determine when bacterial endotoxin testing is needed at your organization. • List the required elements of documentation.
11:30-11:45 am	*Break*	
11:45-12:45 pm	Best Practice Recommendations for Nonsterile Compounding: Enhanced Garbing, Personnel Sampling, Environmental Monitoring and Cleaning	• Evaluate your current garbing, hand hygiene and personnel sampling processes and identify changes that can be made to further reduce the risk to the final CSP and patient. • Understand why more frequent viable air and surface sampling is desirable in a nonsterile to sterile environment. • Adding cleaning program elements such as the need to clean and disinfect after weighing nonsterile powders.
12:45-1:15 pm	*Questions, Answers and Wrap up*	

Total CE hours: 11.25