

Time	Name of Activity	Learning Objectives (for CE Sessions)
90 minutes	Sterile-to-Sterile Compounding <i>ON-DEMAND</i>	<ul style="list-style-type: none"> • Identify situations that are “not compounding” and the new immediate-use category defined in USP 797 (2019), and contrast them with the 2008 requirements. • Differentiate between Category 1 and 2 BUDs described in USP 797 (2019) from the risk levels in the 2008 USP 797 (currently enforceable). • Compare and contrast the 2008 versus 2019 requirements for the use of commercially available SDCs, MDCs, and pharmacy bulk packages. • Contrast drug-strength testing with stability-indicating methods for drug stability. • Define Compounding Records versus Master Formulation Records, and describe CriticalPoint best practices for their implementation. • Describe quality release testing for nonhazardous sterile-to-sterile compounding.
75 minutes	Sterility and Bacterial Endotoxin Testing <i>ON-DEMAND</i>	<ul style="list-style-type: none"> • Describe the difference between direct inoculation and membrane filtration USP 71 sterility testing, and list the benefits of using membrane filtration. • Identify the user-requirement specifications of rapid testing and how they relate to taking a risk-based approach to rapid sterility testing. • Evaluate the need to perform bacterial endotoxin testing on CSPs prepared in your organization.
60 minutes	Quality Systems for Sterile Compounding <i>ON-DEMAND</i>	<ul style="list-style-type: none"> • Define quality assurance and quality control, and develop essential elements of a formal QA/QC system for your organization. • List steps for notification and recall of out-of-specification dispensed CSPs. • Develop a comprehensive, systematic, and written complaint-handling system. • Describe the role of personnel training as it relates to quality assurance. • Summarize how SOPs, documentation, and a change control system are critical to USP 797 compliance.