USP <797>: Compliance and Beyond

USP <797>: Compliance and Beyond is a two-day remote, live, lecture-based training. It is designed to provide the necessary training to implement the 2022 version of USP <797>. Day 1 is designed to highlight all the chapter requirements, ensuring you have a fundamental understanding of the chapter. Day 2 builds on the requirements by discussing industry best practices and providing insight how implementing chapter requirements.

Learning Objectives

Day 1 Chapter Compliance

Section 1 Introduction and Scope (USP 797)
- Identify the CSPs and practices to which the chapter applies.
- List the activities that are beyond the scope of USP <797>.
- Differentiate Category 1, 2, and 3 CSPs.

Section 2 Personnel Training and Evaluation (USP 797)
- Describe the requirements of the two-chapter defined competencies.
- Recall the steps to perform gloved fingertip sampling.
- Identify the appropriate corrective actions in the event of a competency test failure.

Section 3 Personnel Hygiene and Garbing (USP 797)
- List the conditions that prevent an individual from compounding.
- Describe the requirements for personnel preparation and hand hygiene.
- Explain the garbing requirements for Category 1, 2, and 3 compounding.

Section 4 Facilities and Engineering Controls and Section 5 Certification and Recertification (USP 797)
- Describe the facility design requirements for a cleanroom suite and segregated compounding area.
- Differentiate between the primary engineering controls used in sterile compounding.
- List the certification requirements for primary and secondary engineering controls.

Section 6 Microbiological Air and Surface Monitoring (USP 797)
- List when viable air and surface sampling are required.
- Describe the sampling and incubation process for viable air and surface sampling.
- Explain the appropriate steps to take when investigating an exceeded action level.

Section 7 Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Section 8 Introducing Items into the SEC and PEC (USP 797)
- Recall the cleaning frequencies of the different surfaces found in a cleanroom suite and segregated compounding area.
- Choose the appropriate agents and materials to clean primary and secondary engineering controls.
- List the agents and materials needed to transfer items into the primary and secondary engineering controls.

Section 9 Equipment, Supplies and Components (USP 797)
- Describe equipment transfer and use requirements.
- Explain the procedures a sterile compounding facility must have in place for the selection and receipt of supplies and components.
- Recall the steps to take when receiving and evaluating components before use.

Section 10 Sterilization and Depyrogenation (USP 797)
- Differentiate between sterilization and depyrogenation.
- List the biological and chemical indicators that are required for chapter compliance.
- Explain the differences between steam and dry heat sterilization.

Section 11 Master Formulation and Compounding Records (USP 797)
- Explain when master formulation and compounding records are required.
- List the elements of master formulation and compounding records.

Section 12 Release Inspections and Testing (USP 797)
- Describe the importance of performing a second visual inspection before release if a CSP has been stored after compounding.
- Explain the difference between the USP <71> sterility test method and rapid sterility testing.
- Recall when sterility and endotoxin testing are required.

Section 13 Labeling and Section 14 Establishing Beyond-Use Dates (USP 797)
- Identify the required CSP label and labeling components.
- List the parameters that must be considered when assigning beyond-use dates to CSPs.
- Define the beyond-use dates for Category 1, 2, and 3 CSPs.

Section 15 Use of Conventionally Manufactured Products as Components and Section 16 Use of CSPs as Components (USP 797)

- Differentiate between the use of conventionally manufactured products and CSPs as components.
- Assign the proper BUD to preparations made using a CSP as a component.

Section 17 SOPs and Section 18 Quality Assurance and Quality Control
- Define the designated person's and the staff's responsibilities related to SOPs.
- List the quality assurance procedures and quality control activities required of a sterile compounding organization.

Section 19 CSP Handling, Storage, Packaging, Shipping, and Transport
- Discuss CSP storage temperature monitoring considerations.
- Identify the essential elements of SOPs related to the handling, storage, packaging, shipping and transport of CSPs.

Section 20 Documentation
- List the minimal documentation that must be captured by the sterile compounding facility.
- Describe the document storage and retentive expectations.

Day 2 Best Practice Recommendations

Sterile Compounding Quality Management System
- List the best practice elements of a robust quality management system.
- Discuss the how to develop, write, and implement clear, user-friendly SOPs.
- Summarize the chapter documentation requirements.

Personnel Training and Evaluation
- Explain the purpose of personnel training and competency assessments.
- List the best practice recommendations for media-fill testing and gloved fingertip sampling.
- Describe how to best evaluate personnel performance based on their learning needs.

Personnel Hygiene and Garbing
- Recall the proper variations in hand hygiene and garbing based on the sink location.
- Describe the difference between USP <797> current garbing requirements and best practices.
- Articulate to staff the rationale behind hand hygiene and garbing best practices.

Engineering Controls and Certification
- Discuss airflow principles related to primary and secondary engineering controls.
- Explain why best practice design elements should be applied to you compounding area.
- Clearly articulate testing and report requirements with the certification provider.

Microbiological Air and Surface Monitoring
- Discuss the value and limitations of a viable sampling program.
- List the suggested best practice components of a viable sampling program.
- Decide whether fungal media is necessary for use in your viable sampling program.
- Evaluate viable sampling results to identify the best way to address microbial excursions.

Cleaning, Disinfection, and Introducing Items into the SEC and PEC
- Discuss the benefit of applying an EPA-registered one-step sporicidal cleaner to high-touch surfaces on a weekly basis.
- Explain the role of sterile water in a cleaning and disinfecting program.
- List the best practices for transferring materials and equipment into the compounding area.

Sterile Compounding
- Articulate the difference between a beyond-use date and a finish-by date.
- Explain use times of conventionally manufactured single and multi-dose containers and pharmacy bulk packages.
- Identify key elements of aseptic technique to ensure CSPs are safely prepared.

Instructor Biography

Abby Roth, CMQ/OE, founder of Pure Microbiology, has over 18 years of experience in supporting the testing and consulting needs of the pharmaceutical, medical device, and compounding industries. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring. Abby served as a USP Compounding EC member during the 2015-2020 cycle and has been invited to speak for many national organizations.

Agenda

Day 1 Chapter Compliance

30 min	Welcome
30 min	Section 1 Introduction and Scope
30 min	Section 2 Personnel Training and Evaluation
30 min	Section 3 Personnel Hygiene and Garbing
15 min	Break
30 min	Section 4 Facilities and Engineering Controls Section 5 Certification and Recertification
30 min	Section 6 Microbiological Air and Surface Monitoring
30 min	Section 7 Cleaning, Disinfecting, and Applying Sporicidal Disinfectants Section 8 Introducing Items into the SEC and PEC
15 min	Section 9 Equipment, Supplies, and Components
30 min	Lunch
30 min	Section 10 Sterilization and Depyrogenation
15 min	Section 11 Master Formulation and Compounding Records
30 min	Section 12 Release Inspections and Testing
30 min	Section 13 Labeling Section 14 Establishing Beyond-Use Dates
15 min	Break
15 min	Section 15 Use of Conventionally Manufactured Products as Components Section 16 Use of CSPs as Components
30 min	Section 17 SOPs Section 18 Quality Assurance and Quality Control
15 min	Section 19 CSP Handling, Storage, Packaging, Shipping, and Transport
15 min	Section 20 Documentation
15 min	Wrap-up

Day 2 Best Practice Recommendations

15 min	Welcome
60 min	Sterile Compounding Quality Management System
60 min	Personnel Training and Evaluation
15 min	Break
30 min	Personnel Hygiene and Garbing
60 min	Engineering Controls and Certification
30 min	Lunch
60 min	Microbiological Air and Surface Monitoring
60 min	Cleaning, Disinfecting, and Introducing Items into the SEC and PEC
15 min	Break
60 min	Sterile Compounding
15 min	Wrap-up