Pure Primer: Sterile Compounding and Handling Hazardous Drugs

Pure Primer: Sterile Compounding and Handling Hazardous Drugs is a 3.5-day in person training, including lecture and skill building activities. Two and a half days are spent focusing on USP General Chapter <797> requirements, best practices, and implementation strategies; while one day emphasizes the importance of USP General Chapter <800>, exploring requirements and real-life solutions. This interactive training is appropriate for both pharmacists and technicians, especially those who hold a management or designated person role.

Learning Objectives

Day 1

Sterile Compounding: Behind the Medicine
- Articulate how past compounding errors have shaped today's standards of practice and regulations.
- Discuss the challenges sterile compounding entities face in achieving and maintaining chapter compliance.

Sterile Compounding
- Identify the CSPs and practices to which the chapter applies.
- Differentiate between Category 1, 2, and 3 CSPs and define beyond-use dates for these categories.
- Explain use times of conventionally manufactured single- and multi-dose containers, pharmacy bulk packages, and CSPs as components.
- Explain when master formulation and compounding records are required.
- List the elements of master formulation and compounding records.
- Identify the required CSP label and labeling components.

Skill Building: Is It Compounding?
- Review manufacturer's approved labeling and determine if it can be used or if the chapter must be followed.
- Determine if a proposed compounding activity falls within the scope of USP <797>.

Facilities and Engineering Controls
- Describe the non-HD and HD facility design requirements for cleanroom suites, segregated compounding areas, and storage rooms.
- Differentiate between the primary engineering controls used in sterile compounding.
- Explain why best practice design elements should be applied to your compounding area.
- List the C-PECs acceptable for nonsterile and sterile HD compounding.
- Describe the facility requirements for C-SECs used for nonsterile and sterile HD compounding.

Certification of Sterile Compounding Facilities
- List the certification requirements for primary and secondary engineering controls.
- Discuss airflow principles related to primary and secondary engineering controls.
- Describe the tests required for certification of containment primary and secondary engineering controls.

Aseptic Technique
- Identify proper conduct and describe how staff conduct affects the sterile compounding environment.
- Define first air and list the elements that can affect first air within a primary engineering control.

Introducing Items into the SEC and PEC
- List the agents and materials needed to transfer items into the primary and secondary engineering controls.
- Explain how the material transfer process puts the sterile compounding environment at risk of microbial contamination.

Skill Building: First Air and Aseptic Technique
- Identify the direct compounding area in horizontal and vertical flow primary engineering controls.
- Explain how the placement of equipment, components, and supplies affects first air.
- Describe the importance of using slow and controlled movements when working in a primary engineering control.

Day 2

Garbing and Hand Hygiene for USP <797> Compliance
- Recall the proper variations in hand hygiene and garbing based on the sink location and category compounded.
- Describe the difference between USP <797> current garbing requirements and best practices.
- Articulate to staff the rationale behind hand hygiene and garbing best practices.
- List the conditions that prevent an individual from compounding.

Personnel Training and Evaluation
- Describe the requirements of the two chapter-defined hands-on competencies.
- Identify the appropriate corrective actions in the event of a competency test failure.
- Explain the purpose of personnel training and competency assessments.
- List the best practice recommendations for media-fill and gloved fingertip testing and surface sampling.

Skill Building: Garbing, Hand Hygiene, and Personnel Evaluation
- Don sterile gloves in a manner that reduces the risk of contaminating the gloves.
- List the proper sequence for performing hand hygiene and garbing for Category 1 and Category 2 sterile compounding.
- Identify proper technique for the collection of gloved fingertip and thumb samples.

Cleaning, Disinfecting, and Sporicidal Application
- 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.
- 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.

Microbiological Air and Surface Monitoring
- List when viable air and surface sampling are required.
- Discuss the suggested best practice components of a viable sampling program.
- Describe the sampling and incubation process for viable air and surface sampling.
- Explain the appropriate steps to take when investigating an exceeded action level.

Skill Building: Cleaning and Viable Sampling
- Recognize the proper sequence for cleaning a primary engineering control.
- Describe how to properly perform a monthly clean of a cleanroom suite and SCA.
- Recall the proper technique for collecting viable air and surface samples.

Day 3

Inspection and Release Testing
- 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.

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

Skill Building: Seek and Solve Sterile Compounding Challenges
- Note facility design issues and offer solutions for remediation.
- Evaluate a viable sampling plan and modify sample locations to provide more valuable data.
- Identify poorly written SOPs and forms and offer suggestions for improvement.

Skill Building: Sterile Compounding Jeopardy
- Recall USP <797> chapter requirements.
- Identify USP <797> "shoulds" and industry best practices.

Introduction to USP <800> and Handling of HDs
- Identify the major elements of USP General Chapter <800>.
- Differentiate between HD standards, guidelines, and best practices.
- List examples of HD-exposure effects on persons who handle HDs.
- Describe the relationship between the USP compounding chapters and USP <800>.

Applying an Assessment of Risk to HD Compounding
- Identify the essential components of an assessment of risk.
- Differentiate between the drugs that may be exempted from full containment and work practices and those that require full chapter compliance.
- Determine the best method for the creation and maintenance of an AoR for your organization.

Hazardous Drug Work Practices
- Identify work practices that minimize HD contamination and reduce the risk of personnel and patient exposure to hazardous drugs.
- List the types of CSTDs available and identify those best suited for compounding and administration in your organization.
- Describe best practices for effective handling of HDs, including receipt, storage, compounding, administration, and transport.

Skill Building: Wipe Sampling and HD Compounding Techniques
- Describe the chapter recommendations for HD wipe sampling and explain the shortcomings of these recommendations.
- Select wipe sampling locations that will provide valuable information on HD residue containment.
- Explain proper technique for negative-pressure compounding and CSTD use.

Day 4

Decontaminating and Cleaning HD Compounding Environments
- Explain the role of decontamination in containing hazardous drug residue.
- Describe how decontamination relates to the cleaning of the HD compounding environment and identify the proper sequence of applying agents.
- List hazardous drug decontaminating agents.

Hazardous Drug Compounding PPE
- Compare and contrast USP <795>, <797>, and <800> garbing and PPE requirements.
- Identify proper sequence and technique when donning and doffing garb and PPE.
- Discuss garbing and PPE best practices to reduce HD contamination and minimize microbial contamination.

Skill Building: Doffing HD PPE
- Describe the best practice doffing of HD PPE.
- Explain the difference between nonhazardous and hazardous compounding garb and PPE.

Spills and Exposure
- Differentiate between HD spill cleanup requirements and best practices.
- Recall effective spill-management strategies.
- Evaluate current exposure-control and response plans for the required elements.
- Discuss medical surveillance considerations that may be applicable to your organization.

Total CE: 25.5 hours

Agenda

Day 1

8:00–8:30 AM	Welcome
8:30–9:00 AM	Sterile Compounding: Behind the Medicine
9:00–10:15 AM	Sterile Compounding
10:15–10:30 AM	Break
10:30–11:00 AM	Skill Building: Is It Compounding?
11:00 AM–12:30 PM	Facilities and Engineering Controls
12:30–1:15 PM	Lunch
1:15–2:15 PM	Certification of Sterile Compounding Facilities
2:15–3:00 PM	Aseptic Technique
3:00–3:15 PM	Break
3:15–3:45 PM	Introducing Items into the SEC and PEC
3:45–4:45 PM	Skill Building: First Air and Aseptic Technique
4:45–5:00 PM	Wrap-up

Day 2

8:00–9:00 AM	Garbing and Hand Hygiene for USP <797> Compliance
9:00–10:00 AM	Personnel Training and Evaluation
10:00–10:15 AM	Break
10:15 AM–Noon	Skill Building: Garbing, Hand Hygiene, and Personnel Evaluation
Noon–12:45 PM	Lunch
12:45–1:45 PM	Cleaning, Disinfecting, and Sporicidal Application
1:45–2:45 PM	Microbiological Air and Surface Monitoring
2:45–3:00 PM	Break
3:00–4:45 PM	Skill Building: Cleaning and Viable Sampling
4:45–5:00 PM	Wrap-up

Day 3

8:00–8:45 AM	Inspection and Release Testing
8:45–9:45 AM	Sterile Compounding Quality Management System
9:45–10:00 AM	Break
10:00–11:00 AM	Skill Building: Seek and Solve Sterile Compounding Challenges
11:00–11:45 AM	Skill Building: Sterile Compounding Jeopardy
11:45 AM–Noon	Wrap-Up
Noon–12:45 PM	Lunch
12:45–1:00 PM	Welcome
1:00–2:00 PM	Introduction to USP <800> and Handling of HDs
2:00–2:45 PM	Applying an Assessment of Risk to HD Compounding
2:45–3:00 PM	Break
3:00–4:00 PM	Hazardous Drug Work Practices
4:00–4:45 PM	Skill Building: Wipe Sampling and HD Compounding Techniques
4:45–5:00 PM	Wrap-up

Day 4

8:00–9:00 AM	Decontaminating and Cleaning HD Compounding Environments
9:00–10:00 AM	Hazardous Drug Compounding PPE
10:00–10:15 AM	Break
10:15–11:15 AM	Skill Building: Doffing HD PPE
11:15 AM–12:15 PM	Spills and Exposure
12:15–12:30 PM	Wrap-up