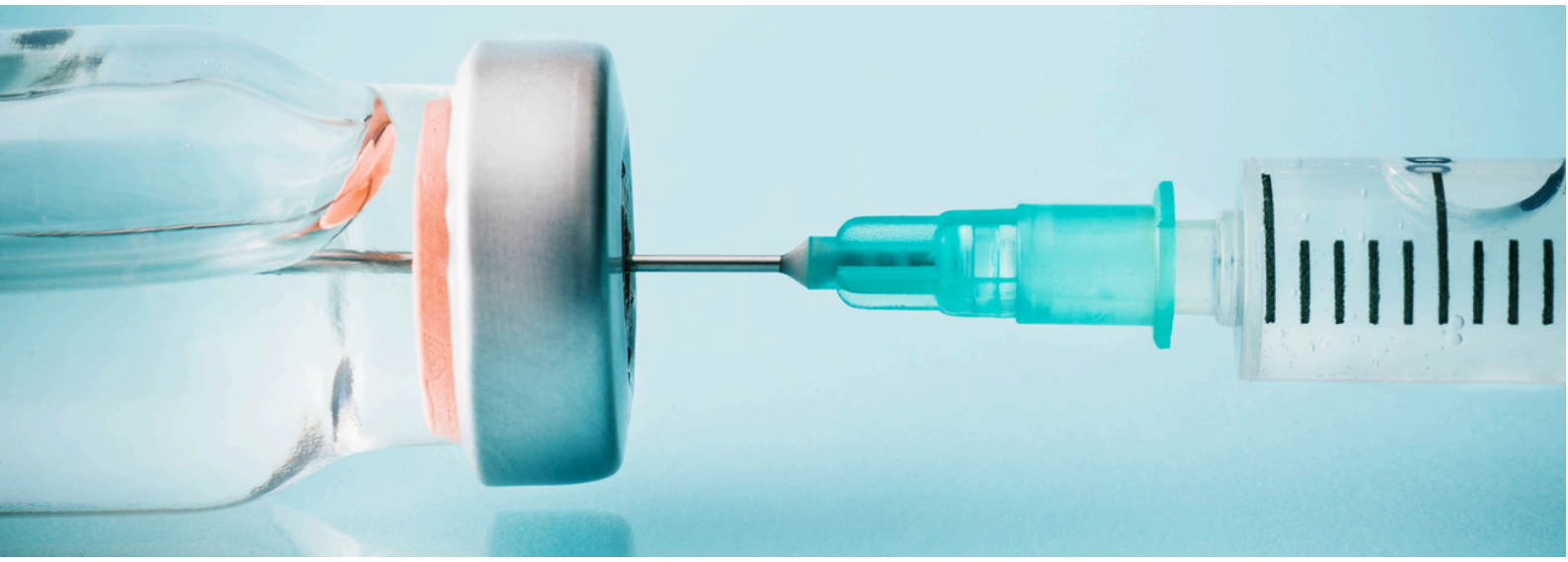
pure microbiology

best practice makes perfect.



PURE PRIMER: STERILE COMPOUNDING AND HANDLING HAZARDOUS DRUGS

Training Guide

PUREMICROBIOLOGY.COM

Dear Pure Primer Participant:

Thank you for registering for Pure Microbiology's Pure Primer: Sterile Compounding and Handling Hazardous Drugs. We are looking forward to meeting you in Bethlehem, Pennsylvania!

This training guide provides the details you need to make travel arrangements. It should also answer any questions you may have about the training.

If you have any questions or concerns, please contact us. We are happy to help.

Sincerely,

Abby Roth, Founder of Pure Microbiology

CONTENTS

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GENERAL TRAINING INFORMATION

GENERAL TRAINING INFORMATION

- A link to PDF copies of all lectures and other relevant resources will be emailed to participants before the training. Paper copies of the lectures are not provided.

- Dress is business casual, but feel free to wear scrubs if you prefer. In addition to lectures, there are also skill-building activities that take place in a training room and a cleanroom. As a result, open toed shoes are not permitted. On day 2, you must wear short sleeves.

- Feel free to bring your computer if you'd like to access the course information during the sessions.

- Work happens. We ask that calls be taken outside of the training rooms.

- Training Facility Address:
  Controlled Environment Certification Services, Inc.
  A Subsidiary of STERIS
  177 North Commerce Way
  Bethlehem, PA 18017

- We are guests in the building. Please respect its facility and parking lot.

- On days 1, 2, and 3, class begins at 8 a.m. and ends at 5:00 p.m. On day 4, class begins at 8 a.m. and ends at 12:30 p.m.

GENERAL TRAINING INFORMATION

- We recommend flying into Lehigh Valley International Airport (ABE). Philadelphia (PHI) and Newark (EWR) are also options, but flying into these locations will require a car rental.

- You will be responsible for your transportation throughout the week.

- The hotel breakfast is included in your daily hotel rate. Pure Microbiology will also provide some breakfast items along with coffee and tea.

- Lunch is catered by a local food establishment. If you have special dietary needs, please contact us at least 2 weeks before the class so we can make appropriate arrangements.

- Dinner is on your own. There are several restaurants in close proximity to the hotel.

- Snacks will be provided during breaks.

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HOTEL

HOTEL

The designated hotel is the Home2 Suites by Hilton Easton.

3882 Eastgate Blvd Bldg 2
Easton, PA 18045
610-258-6100

The room block rate is $149/night + tax.

To make reservations online, please use the link below:

June 2025 Reservations - Please make reservations prior to 05/02/2025.

November 2025 Reservations - Make reservations by 10/10/2025

After this date, any remaining rooms will be released from the block and the discounted rate will no longer be available.

You can also call the hotel directly at 610-258-6100. Then press 0 to reach the Front Desk. Reference the group name **Pure Microbiology** to get the discounted rate.

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AGENDA

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

Agenda subject to change

AGENDA (CONT.)

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

Agenda subject to change

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LEARNING OBJECTIVES

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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.

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.

LEARNING OBJECTIVES

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.

LEARNING OBJECTIVES

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.

LEARNING OBJECTIVES

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.

LEARNING OBJECTIVES

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 decontamination 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

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INSTRUCTORS

MEET THE INSTRUCTORS

ABBY ROTH, CMQ/OE

Abby's lab experience started in 2004 and continued through 2017, where she held the role of Quality Director at a contract pharmaceutical microbiology laboratory. To improve her quality knowledge base, she holds the Certified Manager of Quality/Organizational Excellence certification through the American Society of Quality. Prior to founding Pure Microbiology in 2022, she was a subject matter expert for CriticalPoint LLC, a health care training and development company. In addition to operational responsibilities, she developed curricula for educational sterile compounding products. Abby was also a consultant for Clinical IQ, serving as their Director of Microbiology.

Abby's passion for sterile compounding started in 2008 when USP Chapter <797> introduced the requirement for viable air and surface sampling. This passion really blossomed in 2015 when she had the honor of serving as an expert committee member for the USP Compounding Committee for the 2015 to 2020 cycle. She is an involved member of Controlled Environment Testing Association (CETA), serving on their Board of Directors, speaking at their annual meetings, and chairing committees for the revision of four CETA Application Guides. Abby has been invited to speak for state Boards of Pharmacy and for organizations such as the National Home Infusion Association (NHIA) and the American Society of Health-System Pharmacists (ASHP).

MEET THE INSTRUCTORS

PATRICIA CLANCY KIENLE, RPH, MPA, BCSCP, FASHP

Patricia Kienle is the Director of Accreditation and Medication Safety for Cardinal Health.

She received her pharmacy degree from the Philadelphia College of Pharmacy and Science and a master's in Public Administration from Marywood University in Scranton, Pennsylvania. She is board certified as a Sterile Compounding Pharmacist, completed an executive fellowship in Patient Safety from Virginia Commonwealth University in Richmond, Virginia, and is an Adjunct Clinical Faculty member at Wilkes University in Wilkes-Barre, Pennsylvania. She served on the Board of Directors of the American Society of Health-System Pharmacists and as President of the Pennsylvania Society of Hospital Pharmacists. She is a Fellow of ASHP, was named Pharmacist of the Year by PSHP, the recipient of the Distinguished Achievement Award in Hospital and Institutional Practice from the American Pharmaceutical Association Academy of Pharmacy Practice and Management, the Distinguished Leadership Award from ASHP, the ASHP John W. Webb Lecture Award, the Thomas S. Foster Award from the United States Pharmacopeia, the Lifetime Achievement Award from the Institute for Safe Medication Practices, and ASHP Harvey A.K. Whitney Lecture Award. She has served on the Pharmacotherapy Specialty Council of the Board of Pharmacy Specialties, the Pennsylvania Patient Safety Authority, the Hospital Professional and Technical Advisory Committee of The Joint Commission, and on the Board of Governors of the National Patient Safety Foundation. She is a current member of the USP Compounding Expert Committee.

Patti is the author of *The Chapter <795>; Answer Book*, *The Chapter <797>; Answer Book*, *The Chapter <800>; Answer Book*, and co-author of *Meeting Accreditation Standards: A Pharmacy Preparation Guide*.

With over 600 invited presentations and 100 publications, she has special interests in promoting medication safety, compounding sterile preparations, accreditation, and regulatory issues.

MEET THE INSTRUCTORS

KEVIN N. HANSEN, PHARMD, MS, BCSCP

Kevin N. Hansen, PharmD, MS, BCSCP is a distinguished expert in pharmaceutical compounding with over 15 years of experience in health-system pharmacy operations. He has a profound interest in patient safety and drug shortage mitigation, and he is renowned for his successful implementation of compounding technology and automation, particularly a centralized IV sterile compounding robot operation at a large health system.

Dr. Hansen's expertise extends to designing cleanroom suites for USP <797> and <800> compliance, and he has designed over 10 such facilities. He is a board-certified expert in compounded sterile preparations through the Board of Pharmacy Specialties, and he completed a PGY1/PGY2 Health-System Pharmacy Administration and Leadership residency program at the University of North Carolina Medical Center. Dr. Hansen earned his Doctor of Pharmacy degree from Lake Erie College of Osteopathic Medicine (LECOM) and a Master of Science degree in Pharmaceutical Sciences with a specialization in health-system pharmacy administration from the UNC Eshelman School of Pharmacy.

In addition to his professional accomplishments, Dr. Hansen serves as adjunct faculty for the UNC Eshelman School of Pharmacy, where he imparts his knowledge and expertise to aspiring pharmacy leaders. He is also currently serving as an expert volunteer on the United States Pharmacopeia (USP) Compounding Expert Committee. Dr. Hansen is a proven leader and is passionate about leading multidisciplinary teams to achieve success in health-system pharmacy operations.

MEET THE INSTRUCTORS

LEW EXNER

A Navy veteran and a seasoned trainer and leader, Lew brings over 30 years of experience specializing in cleanroom and containment device certification. He has held several accreditations with NSF, NEBB and CETA. Lew started as a field technician making his way up as a Certification Division Manager managing over 35 employees. He was instrumental in developing a Cleanroom Technician Training program and has performed thousands of airflow visualization smoke studies in both Pharmaceutical (cGMP) and Pharmacy (503A and 503B) clients.

Lew is currently the Director of Field Operations at Controlled Environment Consulting (CEC) overseeing the certification service and training operations. Over the course of his career, he has become a well-known and respected consultant for certification and validation environments. Lew has presented several classes designed to enhance the general certification knowledge for the FDA and has been an instructor for “Testing HEPA Filtered Systems and Pharmaceutical Cleanrooms” at the Eagleson Institute since 2003.

Lew served on the Controlled Environment Testing Association (CETA) Working Group for the Ceta Application Guide (CAG-008). Lew has served on the Controlled Environment Testing Association, (CETA) Board of Directors since 2021 and was President of CETA for the 2024 – 2025 term.