

PREMIER

Course Guide | 2027 Edition

Sterile Compounding and Hazardous Drug Handling

Moving beyond textbook compliance to REAL-world practice and leadership.

Welcome



Dear Participants,

Thank you for registering for Premier's ***Sterile Compounding and Hazardous Drug Handling*** training course. We're excited to welcome you to Bethlehem, PA, for a practical, application-focused program designed to strengthen your sterile compounding knowledge and hazardous drug handling practices.

This guide provides the course details you'll need to prepare for the program, arrange your travel and plan your time on-site.

If you have questions before the course, please reach out. We're glad to assist and look forward to welcoming you.

Sincerely,

Your Course Instructors

Inside This Guide

- Course information.
- On-site logistics and travel.
- Agenda.
- Learning objectives.
- Meet the instructors.
- Additional resources.

Our Training Philosophy

Moving beyond textbook compliance to REAL-world practice and leadership.

Traditional sterile compounding education is often purely theoretical. Our differentiated approach closes that gap: every session connects what the standard requires to how it's performed at the bench, run in daily operations and sustained through leadership.
We call it **REAL**.

The REAL Model



R — **Requirements and Knowledge**
The baseline standards, regulatory framework and foundational science.

E — **Execution and Technique**
Bench-level mechanics, tactile precision and physical competencies.

A — **Application and Operations**
Translating rules into daily workflow, systems management and throughput.

L — **Leadership and Culture**
Quality culture, accountability, supervisory oversight and human factors.

Coursework that stops at the textbook leaves participants to figure out practice on their own. Our training course, REAL, links each requirement to hands-on technique, day-to-day operations and the leadership that sustains a quality culture, so learning transfers directly to your compounding area.

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Course Information



REAL: Sterile Compounding and Hazardous Drug Handling is a three-and-a-half-day, in-person training that combines lecture with hands-on skill-building activities. Two and a half days focus on USP General Chapter <797> requirements, best practices and implementation strategies, while one day emphasizes USP General Chapter <800>. The program is appropriate for pharmacists and pharmacy technicians, particularly those serving in a management or designated person role.

3.5 days	25.5 hours	2.5 days	One day
In-person training	CE credits	USP <797> focus	USP <800> focus

Continuing Education Credits — 25.5 Hours

Pharmacists and pharmacy technicians must complete the course evaluation in order to receive continuing education credit. Instructions for completing the evaluation will be provided on-site and emailed following the course.

ACPE Accreditation

This course is ACPE-accredited. Statements of credit will be posted to CPE Monitor following completion of the course evaluation. Please confirm that your NABP e-Profile ID and date of birth are accurate before the program begins, as credit can't be awarded without them.

Course Materials

A link to PDF copies of all lectures and supporting resources will be emailed to participants approximately one week before the course. Printed copies of the lectures aren't provided.

Pre-course Survey

Participants are asked to complete the pre-course survey. Your responses allow us to tailor the training to the types of sterile compounding operations represented and to accommodate individual needs, including garbing sizes, dietary restrictions and food allergies, and any other accommodations you wish to share.

Before you arrive: Complete the pre-course survey and verify your NABP e-Profile ID.

On-site Logistics



Location

The course will be held at **Integra CE Services** offices, located at

177 N. Commerce Way,
Bethlehem, PA 18017

Parking

There are multiple visitor parking spots available at the front left side of the building.

Building Access

The guest entrance is at the front of the building, just off the main road. The building will open to participants at 7:40 a.m. ET. Badge access is required for entry. An Integra employee will greet you at the entrance upon arrival. Participants who leave the building during breaks must contact an Integra employee to be readmitted.

Meals and Snacks

Light breakfast items will be available each morning. Snacks and beverages will be available throughout the day, and coffee and tea may be accessed in the break area. Lunch will be provided on Days 1–3 of the training. Dinner is on your own.

Attire

Attire is business casual; scrubs are also appropriate. In addition to lectures, the program includes hands-on **skill-building** activities, for which scrubs may be more comfortable.

Computers

Participants are welcome to bring a laptop to access course materials during the sessions. Electrical outlets are available for charging.

Private Office Space

Full participation in the training is encouraged; however, we recognize that business needs may arise. A small office is reserved for on-site use as needed.

Property Rules

Smoking and vaping are permitted only in the designated smoking area at the back of the building. Please refrain from smoking or vaping near or around the building. Recycling receptacles are available.

Travel and Lodging

Airport

Lehigh Valley International Airport (ABE), approximately 10 minutes from the Integra CE offices.

Ground Transportation

Ride share and rental car are both available.

Hotel Accommodations

Premier Negotiated Rate | Book Through Egencia



Tru by Hilton Easton

★★★★ 4.2/5 on Tripadvisor

Check-in/out: 3 p.m. / noon

Amenities: Wi-Fi · Parking · Free hot breakfast · Indoor pool



Home2 Suites by Hilton Allentown Bethlehem Airport

★★★★ 3.9/5 on Tripadvisor

Check-in/out: 3 p.m. / 11 a.m.

Amenities: Wi-Fi · Parking · Free hot breakfast · Indoor pool



SpringHill Suites by Marriott

★★★★½ 4.6/5 on Tripadvisor

Check-in/out: 4 p.m. / 11 a.m.

Amenities: Wi-Fi · Parking · Free hot breakfast · Indoor pool

Book through Egencia. Register your Guest Traveler profile first, then log in to view all Premier-negotiated properties.

Local Tip: Check out the downtown Bethlehem area, which includes ArtsQuest, Moravian bookstore and a variety of restaurants!

Booking Your Hotel Through Egencia

Attendees can access Premier's negotiated hotel rates by booking through Egencia, Premier's corporate travel platform. **You will receive your Egencia booking link by email after you register for the course.**

How It Works

1

Register for the Course

Complete your live training registration. Course registration does not automatically create an Egencia travel profile.

2

Watch for Your Egencia Link

Your registration confirmation email will include the link to set up your Egencia account.

3

Create Your Profile

Use the link to create your Egencia traveler profile. Your account is ready to use as soon as it's created.

4

Book Your Hotel

Reserve your room in Egencia, where Premier's negotiated rates are already loaded.

Questions About Booking?

Email trvldep@premierinc.com

Phone 669.288.7558

Agenda

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

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

Agenda subject to change.

Agenda

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

Day 4	8 a.m. – 12:30 p.m.
8 – 9 a.m.	Decontaminating and Cleaning HD Compounding Environments
9 – 10 a.m.	Hazardous Drug Compounding PPE
10 – 10:15 a.m.	*Break*
10:15 – 11:15 a.m.	**Skill Building**: Doffing HD PPE
11:15 a.m. – 12:15 p.m.	Spills and Exposure
12:15 – 12:30 p.m.	Wrap-up

Agenda is subject to change. Lunch is provided daily except on Day 4. Please wear comfortable attire or scrubs for hands-on **skill-building** sessions.

Day 1

Course Overview: REAL: Sterile Compounding and Hazardous Drug Handling is a three-and-a-half-day, in-person training that combines lecture and hands-on **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.

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 compounded sterile preparations and define beyond-use dates for these categories.
- Discuss master formulation records, compounding records and labeling requirements.

Skill Building · Activity

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>.

Task: The instructor presents a series of scenarios commonly encountered in sterile compounding operations. Participants evaluate each scenario to determine whether the manufacturer's approved labeling may be followed or whether the requirements of USP <797> apply.

Goal: Determine whether each proposed activity falls within the scope of USP <797> and identify the applicable compounding requirements.

Discussion: The instructor shares the correct response for each scenario and leads a discussion about the rationale, including common areas of confusion and the potential compliance implications of an incorrect determination.

Day 1 (continued)

Facilities and Engineering Controls

- Describe the nonhazardous and hazardous 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 containment primary engineering controls acceptable for nonsterile and sterile hazardous compounding.
- Describe the facility requirements for containment secondary engineering controls used for nonsterile and sterile hazardous 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.

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.

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.

Day 1 (continued)

Skill Building · Activity

First Air and Aseptic Technique

- Identify the direct compounding area (DCA) 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.



Activity 1

Making the Invisible Visible

Task: Participants observe instructors utilizing a visible medium to highlight the airflow in different PECs, including those with equipment and excessive supplies. Participants can also use the visible medium generator. Particle counter will also be available as a tool to understand particle generation during certain common cleanroom activities.

Goal: Recognize good airflow to the DCA and any issues that may be present in a crowded PEC.

Discussion: Instructors will lead discussion during the demonstration, focusing on first air challenges, backstreaming concerns and particle generation.

Activity 2

Recognizing the Diversity of Compounding Technique

Task: Participants will observe instructors demonstrating different compounding techniques in a PEC and be given an opportunity to try their hand at compounding.

Goal: Identify the different compounding techniques and recognize the risks that come with each.

Discussion: Instructors will lead discussion during the demonstration, focusing on first air, compounding technique and the use of compounding supplies, such as dispensing pins.

Learning Objectives

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.



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.
- List the best-practice recommendations for media-fill and gloved fingertip testing.

Skill Building · Activity

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.
- Discuss proper hand-washing techniques.
- Identify proper technique for the collection of gloved fingertip samples.

Day 2 (continued)

Activity 1

Can You Successfully Don Sterile Gloves?

Task: Participants observe the proper glove donning procedure and practice under the supervision of the instructor. Instructions on proper gloved fingertip sample collection are provided.

Goal: Successfully don sterile gloves and collect gloved fingertip samples from one another, which will be incubated.

Discussion: Results of the gloved fingertip and thumb sampling will be shared with the participants on Day 4 of the training.

Activity 2

Risk-based Garbing Order and Hand-washing

Task: Participants walk through possible garbing orders based on facility design with the instructor: sink outside the anteroom, sink on the dirty side of the line of demarcation, sink on the clean side of the line of demarcation. Participants will use a product meant to simulate contamination on your hands and practice proper hand-washing techniques to remove it.

Goal: Identify garbing challenges and risks to the compounding environment in each scenario and frequently missed spots during hand hygiene.

Discussion: The instructor will lead a discussion justifying the facility's garbing order. After hand-washing, a blacklight will be used to evaluate hand-washing effectiveness.



Learning Objectives

Day 2 (continued)



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 Environmental Protection Agency-registered one-step sporicidal cleaner to high-touch surfaces on a weekly basis.

Microbiological Air and Surface Monitoring

- List when viable air and surface sampling are required.
- Discuss the 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 · Activity

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 segregated compounding area.
- Recall the proper technique for collecting viable air and surface samples.

Day 2 (continued)

Activity 1

Cleaning the Compounding Environment

Task: Participants evaluate and demonstrate the proper sequence for cleaning a primary engineering control and performing a monthly cleaning of a cleanroom suite or segregated compounding area.

Goal: Apply the appropriate cleaning sequence, agents, materials and techniques to primary and secondary engineering controls.

Discussion: The instructor leads a discussion about cleaning order, agent and material selection, contact time, surface coverage, and common technique failures that may compromise cleaning effectiveness.

Activity 2

Viable Air and Surface Sampling

Task: Participants practice the proper technique for collecting viable air and surface samples within a sterile compounding environment.

Goal: Collect viable air and surface samples using techniques that support representative and reliable environmental monitoring results.

Discussion: The instructor discusses representative sampling locations, sampling technique, media handling, incubation considerations and factors that may produce unreliable viable air or surface sampling results.



Day 3

Inspection and Release Testing

- Describe the importance of performing a second visual inspection before release if a compounded sterile preparation 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 standard operating procedures (SOPs).
- Define the designated person's and the staff's responsibilities related to standard operating procedures.
- List the quality assurance procedures and quality control activities required of a sterile compounding organization.

Skill Building · Activity

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.

Activity 1

Facility Design Review

Task: Participants review examples of sterile compounding facilities, identify facility design deficiencies and propose practical corrective actions.

Goal: Recognize facility design conditions that may create compliance or contamination-control risks and recommend appropriate remediation.

Discussion: Participants share their findings and proposed solutions. The instructor connects the identified conditions to USP <797> facility requirements, certification considerations and industry best practices.

Day 3 (continued)

Activity 2

Viable Sampling Plan Review

Task: Participants evaluate a viable air and surface sampling plan and determine whether the selected locations will provide meaningful information about the state of microbial control within the compounding environment.

Goal: Identify weaknesses in a viable sampling plan and select sampling locations that provide representative and actionable environmental monitoring data.

Discussion: The instructor leads a discussion about risk-based sample site selection, representative locations, high-risk surfaces, airflow considerations and the limitations of sampling plans that do not adequately reflect compounding activities.

Activity 3

SOP and Form Review

Task: Participants review an example of standard operating procedures and controlled forms, identify weaknesses and recommend revisions.

Goal: Recognize documentation practices that may lead to inconsistent performance, incomplete records or difficulty demonstrating compliance.

Discussion: The instructor reviews the participants' observations and discusses the characteristics of clear, complete, user-friendly procedures and forms that support consistent practices and effective quality oversight.

Skill Building · Activity

Sterile Compounding Jeopardy

- Recall USP <797> chapter requirements.
- Identify USP <797> "shoulds" and industry best practices.

Task: Participants work in teams to answer questions covering USP <797> requirements, chapter recommendations and sterile compounding best practices.

Goal: Reinforce recall of key chapter requirements and distinguish mandatory requirements from recommendations and industry best practices.

Discussion: The instructor reviews the correct response and rationale for each question, clarifies areas of confusion, and discusses how the requirements and best practices apply to routine sterile compounding operations.

Learning Objectives

Day 3 (continued)

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 (AoR).
- 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 · Activity

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.

Day 3 (continued)

Activity 1

Hazardous Drug Wipe Sampling

Task: Participants use provided wipe sampling materials to collect hazardous drug residue samples from designated surfaces. Participants follow the supplied instructions for defining the sampling area, moistening and handling the wipe, collecting the sample using a consistent wiping pattern, and packaging and labeling the sample for analysis.

Goal: Demonstrate proper hazardous drug wipe sampling technique and recognize the procedural factors that support consistent, representative and usable results.

Discussion: The instructor reviews the participants' sampling technique and discusses selection of the sampling location, use of a defined surface area, wipe coverage and pressure, prevention of cross-contamination, sample labeling and handling, and documentation. The group also discusses how inconsistent collection practices can affect the interpretation and comparability of wipe sampling results.

Activity 2

Hazardous Drug Compounding Techniques

Task: Participants prepare simulated hazardous drug compounds using a closed-system drug-transfer device (CSTD) and negative-pressure technique and prime IV tubing using a technique intended to minimize hazardous drug exposure. Under instructor supervision, participants connect and operate the CSTD, withdraw and transfer solution, prime the tubing, and use negative-pressure technique while maintaining appropriate material placement and aseptic practices within the containment primary engineering control.

Goal: Demonstrate correct use of a CSTD, negative-pressure technique and a safe method for priming IV tubing to reduce the potential for hazardous drug escape while maintaining aseptic technique and protection of critical sites.

Discussion: The instructor reviews the participants' technique and discusses correct CSTD assembly and use, maintenance of negative pressure, and methods for priming IV tubing while minimizing hazardous drug exposure. The discussion also addresses prevention of leaks and aerosol generation, protection of critical sites, management of air within the tubing, and safe disconnection and disposal practices. The group compares how CSTDs, negative-pressure technique and tubing-priming practices contribute to containment and identifies errors that may increase the risk of hazardous drug contamination or compromise sterility.

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 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 · Activity

Doffing HD PPE

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

Task: Participants observe the proper sequence for doffing hazardous drug personal protective equipment and then practice the process under instructor supervision. Before doffing, a fluorescent product that simulates hazardous drug residue is applied to designated areas of each participant's gown and gloves. After doffing, participants' hands are examined under a blacklight to identify any simulated residue transferred during the process.

Goal: Remove hazardous drug PPE in a sequence and manner that reduces the potential for transferring hazardous drug residue to the hands, clothing or surrounding environment, and use blacklight findings to evaluate the effectiveness of the participant's doffing technique.

Discussion: The instructor reviews the blacklight findings with participants and discusses any locations where simulated hazardous drug residue was transferred to the hands during doffing. The group identifies the steps or contact points that may have contributed to contamination and reviews techniques for improvement. The discussion also addresses common doffing errors, differences between hazardous and nonhazardous compounding garb and PPE, hand hygiene, contamination control, and appropriate disposal of used 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.

Continuing Education Credit



25.5 hours

Continuing Education Credits

Complete the course evaluation to receive credit.



Abby Roth

Credentials

- Certified Manager of Quality / Organizational Excellence
- CETA Board of Directors
- USP Compounding Committee 2015-2020

Meet the Instructors

Abby Roth, CMQ/OE

Executive Director, Pure Microbiology

Premier

Abby Roth, CMQ/OE, is Executive Director of Pure Microbiology at Premier, where she provides consulting, training and auditing services to support sterile compounding and microbiology programs. She has supported the pharmaceutical, medical device and compounding industries since 2004, with expertise in environmental monitoring, contamination control, quality systems and regulatory compliance.

Before founding Pure Microbiology, Abby served as both Laboratory Director and Quality Director at a contract microbiology laboratory, where she led laboratory operations and quality initiatives. She also worked as a consultant with Clinical IQ and served as a subject matter expert with CriticalPoint, helping organizations strengthen microbiology practices and sterile compounding compliance.

Abby founded Pure Microbiology in 2022 to provide practical, science-based support to pharmacies and other healthcare organizations. Pure Microbiology became part of Premier in 2025, expanding the reach of its education and consulting services. Abby has served on the USP Compounding Expert Committee and is an active leader within CETA, contributing to industry standards and guidance. She is a nationally recognized speaker for boards of pharmacy and professional organizations and holds an ASQ Certified Manager of Quality/Organizational Excellence certification.

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Kevin Hansen

Credentials

- Board Certified Sterile Compounding Pharmacist
- National Speaker and Educator
- Former System Director of Pharmacy

Meet the Instructors

Kevin Hansen, Pharm.D., M.S., BCSCP

Senior Director, Pharmacy Compounding, Operations & Technology Services

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Kevin N. Hansen, Pharm.D., M.S., 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.

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. 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, 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. Hansen is a proven leader and is passionate about leading multidisciplinary teams to achieve success in health-system pharmacy operations.

PREMIER



Katrina Harper

Credentials

- USP <797>, <795>, <800> Compliance and Compounding Expertise
- Medication Safety and Drug Diversion Prevention Specialist
- Regulatory Compliance and Accreditation Readiness
- Pharmacy Operations Optimization Leader
- 17+ Years Health-system Pharmacy Leadership

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Meet the Instructors

Katrina Harper, Pharm.D., MBA, BCPS

Director, Pharmacy Compounding Services – Advisory

Premier

Katrina Harper, Pharm.D., MBA, BCPS, is a recognized pharmacy leader with more than 17 years of healthcare experience spanning clinical practice, pharmacy operations, medication safety, regulatory compliance and health-system leadership. She currently serves as Director of Pharmacy Compounding Services - Advisory at Premier, where she provides pharmaceutical and clinical expertise to internal stakeholders and member organizations, with a primary focus on pharmaceuticals and other clinically related product categories.

Throughout her career, Harper has held a variety of progressive leadership positions, including Pharmacy Manager for a community pharmacy chain, Director of Pharmacy for a cardiovascular specialty hospital, and Medication Safety Officer for a large academic safety-net county hospital. Her diverse experience has provided her with extensive expertise in medication-use systems, patient safety initiatives, operational optimization and regulatory compliance across multiple healthcare settings.

Harper is a respected educator and industry contributor who has served as chairperson and adjunct faculty for an ASHP-accredited Pharmacy Technician program. She is also the recipient of the Texas Society of Health-System Pharmacists' Larry C. Nesmith Pharmacist Recognition Award, recognizing her contributions to pharmacy practice and leadership.

Her areas of expertise include safe medication management, medication security and drug diversion prevention, process improvement, pharmacy operations optimization, and regulatory compliance, with a specialized focus on the USP Compounding Compendium. In her work with health systems and pharmacy professionals, Harper helps organizations strengthen compliance programs, improve operational performance, and implement best practices that enhance patient safety and quality outcomes.

Harper earned her Doctor of Pharmacy degree from Xavier University of Louisiana College of Pharmacy and her Master of Business Administration from The University of Texas at Arlington. She is also a Board Certified Pharmacotherapy Specialist (BCPS).



Lew Exner

Credentials

- 30+ Years in Cleanroom and Containment Device Certification
- NSF, NEBB and CETA Accreditations
- Navy Veteran, Trainer and Leader
- CETA Board Member since 2021; President 2024–2025

Meet the Instructors

Lew Exner

Director of Field Operations

Controlled Environment Consulting (CEC)

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 more than 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.

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Questions?

Contact Abby Roth at **abby_roth@premierinc.com** for any questions or assistance.

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