

APRIL 23-26, 2018 | PHOENIX, ARIZONA

Educate. Engage. Empower.

2018 NHIA ANNUAL
CONFERENCE

Sterile Compounding Clinic 4-Day Program

Sunday, April 22

1:00 PM – 5:00 PM **Registration Check-in**

5:30 PM – 7:30 PM **Welcome Reception**

Join old friends and colleagues and welcome new attendees to this year's NHIA Annual Conference during a meet-and-greet gathering to kick-off this year's exciting program. Relax and enjoy refreshments, appetizers, and great conversation. Hosted by the NHIA Board of Directors in honor of the Future of Infusion Advisory Council.

Monday, April 23

Day 1 Sterile Compounding Clinic Agenda

7:30 AM – 4:00 PM **Sterile Compounding Regulatory Forum**

Day 1 of the NHIA Sterile Compounding Clinic (which is also being offered as a stand-alone seminar for executives and managers) will provide a big picture overview about the current and future state of sterile compounding and will provide essential knowledge regarding the rules and regulations that will impact organizations.

Faculty: Eric Kastango, MBA, RPh, FASHP, President & CEO, Clinical IQ, LLC; Mike Koch, RPh, MBA, Senior Vice President, Professional Services, CAPS; Barbara Petroff, MS, RPh, FASHP; Julie Dohm, JD, Ph.D., Senior Science Advisor for Compounding, FDA

7:30 AM – 8:00 AM **Welcome, Announcements, Introductions & Breakfast**

Faculty: Connie Sullivan

8:00 AM – 8:30 AM **The Evolution of Compounding Regulations: How Did We Get Here?**

Faculty: Eric Kastango

A look back at how sterile compounding standards and regulations have evolved and the milestone events that have led to us to where we are today.

8:30 AM – 9:30 AM

The Regulatory Playing Field

Faculty: Eric Kastango

An overview of the various entities involved in regulating sterile compounding practice and recommendations for how providers in every setting can navigate the changing landscape.

9:30 AM – 9:45 AM

Break

9:45 AM – 11:00 AM

What's Wrong with This Picture?

Faculty: Eric Kastango and Barbara Petroff

A visual tour of what to do, and what not to do in a sterile compounding practice.

11:00 AM – 11:45 AM

The State of Hazardous Drug Compounding Regulations

Faculty: Barbara Petroff

With the implementation of USP <800> officially delayed and USP <797> still pending, how can providers prepare for new hazardous drug compounding regulations?

11:45 AM – 12:30 PM

Lunch

12:30 PM – 2:00 PM

Compounding Guidance from the Food and Drug Administration

Faculty: Julie Dohm

Insights from the FDA regarding the future direction of regulations for 503A and 503B compounders.

2:00 PM – 2:15 PM

Break

2:15 PM – 4:00 PM

Is the Future 503B?

Faculty: Mike Koch

This program will examine the evolution of 503B entities and their regulatory requirements so attendees can assess whether registering is right for their business.

4:15 PM – 5:45 PM

NHIA Annual Conference Opening General Session

5:45 PM – 7:45 PM

Grand Opening Reception – NHIA Annual Conference – Exhibit Hall

Network with colleagues while enjoying complimentary drinks and hors d'oeuvres. This is the prime time for you to visit with a select group of exhibitors that support the home and specialty infusion industry. Visit the Exhibit Hall throughout the week to discover the products and services from the more than 100 companies that will be exhibiting

Tuesday, April 24

Day 2 Sterile Compounding Clinic

- 7:00 AM – 9:00 AM** Optional for Sterile Compounding Clinic Attendees
3M Sponsored Breakfast – Product Tutorial
Management of Central Venous Access Device-Associated Skin Impairment: An Evidence-Based Algorithm – Daphne Broadhurst RN, BScN CVAA (c)
- 9:15 AM – 10:15 AM** **Sterile Compounding Clinic: Aseptic Practices**
Faculty: Barbara Exum
This session provides attendees with a comprehensive review of the specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens during the compounding process.
- 10:30 AM – 11:30 AM** **Sterile Compounding Clinic: Facility Design & Maintenance**
Faculty: Mala Crossley, PharmD, VP Payer Relations, Elwyn Pharmacy Group; Marc Stranz, PharmD, VP Clinical, Elwyn Pharmacy Group/BioMatrix Specialty Pharmacy
Everything you need to know about how to design a compliant cleanroom facility and create a workflow process based on USP standards and best practices.
- 11:30 AM – 3:00 PM** **Sterile Compounding Clinic: Lab**
Attendees will rotate through a simulated lab environment with qualified instructors to practice hand hygiene and garbing, performing aseptic transfers, cleaning and disinfecting the PEC, conducting smoke studies, taking surface samples and more. The lab offers a unique opportunity to work in several types of primary engineering controls so attendees can gain experience compounding with different techniques.
- 3:15 PM – 4:45 PM** **Sterile Compounding Clinic: Decontamination, Cleaning and Disinfecting**
Faculty: Mark Wiencek, Ph.D. and David P. Nobile
Take the confusion out of cleaning agents and methods and learn the correct and most efficient way to remove contamination, clean and disinfect your cleanroom facility and equipment.
- 5:00 PM – 6:30 PM** **Roundtables**
Engage in networking and shared-learning as you discuss common interests, address challenges, and consider critical issues facing your business and the field today.
- 6:30 PM – 7:45 PM** **NHIF Raise the Foundation Cocktail Reception**
(tickets required).

Wednesday, April 25

Day 3 Sterile Compounding Clinic

9:15 AM – 10:45 AM **NHIA Annual Conference – General Session**

10:45 AM – 1:15 PM **Sterile Compounding Clinic: Lab**

1:30 PM – 3:00 PM **Sterile Compounding Clinic: Environmental Monitoring Faculty:** Abby Roth

This session will provide attendees with a comprehensive review of the essential elements of a sterile compounding environmental monitoring program in accordance with current and proposed draft United States Pharmacopeial (USP) standards. Attendees will also learn how to employ a quality assurance program to demonstrate a “state of control” in all critical areas of the cleanroom.

3:15 PM – 4:45 PM **Sterile Compounding Clinic – Employee Training & Qualification**

Faculty: Kurstin M. Peplinski, BS, CPhT, Senior Ambulatory Training Specialist, Fairview Pharmacy Services

This session will prepare attendees to implement a comprehensive employee training and qualification program for working in classified areas and performing aseptic procedures to prepare compounded sterile products in compliance with current USP standards.

5:00 PM – 6:30 PM **NHIA Roundtables**

7:00 PM – 10:00 PM **NHIA NETWORKING EVENT**

Join us at Rustler’s Rooste, Arizona’s Legendary Cowboy Steakhouse, for food, drinks, and great conversation. This is a perfect environment to reconnect with old friends and meet new ones while enjoying unparalleled view of the city lights and fun cowboy games.

Thursday, April 26

Day 4 Sterile Compounding Clinic

7:00 AM– 9:00 AM **Sterile Compounding Clinic: Sterility Testing and Determining BUDs**

Faculty: Eric Bauer, RPh, Senior Consultant, CAPS

This session will provide attendees with a risk-based approach to determining an appropriate beyond-use-date for compounded sterile products, including parenteral nutrition, in accordance with current and proposed draft United States Pharmacopeial (USP) standards. Attendees will also learn about the various sterility testing methods used to extend BUDs and when and how to apply them in their operations.

9:15 AM – 10:45 AM **Sterile Compounding Clinic: Hazardous Drug Compounding**

Faculty: Barbara Petroff and L. Rad Dillon, RPh, ASQ CMQ/OE, ASQ CQA, ACHC Surveyor and Pharmacy Consultant, ACHC)

Review the ins and outs of the new USP <800> standard and how to adapt your operation for compliance.