Compounding Pharmacy Compliance

June 18-19, 2024 | Boston, MA
Revere Hotel Boston Common

Pending ACPE Credits

Conquer Regulatory Complexities and Mitigate Risk by Developing First-Class Compliance and Quality Standards

Ensure inspection readiness at the preeminent event for compounding professionals

Gain timely regulatory updates, innovative technology solutions, industry best practices and protocols to drive quality assurance facility-wide.

Thought-provoking conversations led by expert speakers, including:

Lauren Pearson, PharmD., MBA
Senior Scientist I, Personalized Medicines
US Pharmacopeia

Jay Bhaumik
CEO
Texas Star Pharmacy

Sophia Flores
Director of Manufacturing Operations
QuVa Pharma

Renee Barker, PharmD, BCSCP
Member
California State Board of Pharmacy

Masoud Rashidi, PharmD
Chief Compounding Pharmacist
Innovative Compounding Pharmacy

Pallavi Badkar
Vice President of Operations
Medisourcerx

Scott Shepard
Director of Home Infusion Service,
Beth Israel Lahey Health

Jules D'Souza
503A Quality Director
Empower Pharmacy

PLUS! Customize your learning experience through our 503A and 503B tracks

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Updated 4/25/24

About the Event

The Industry-Leading Event for Compounding Professionals

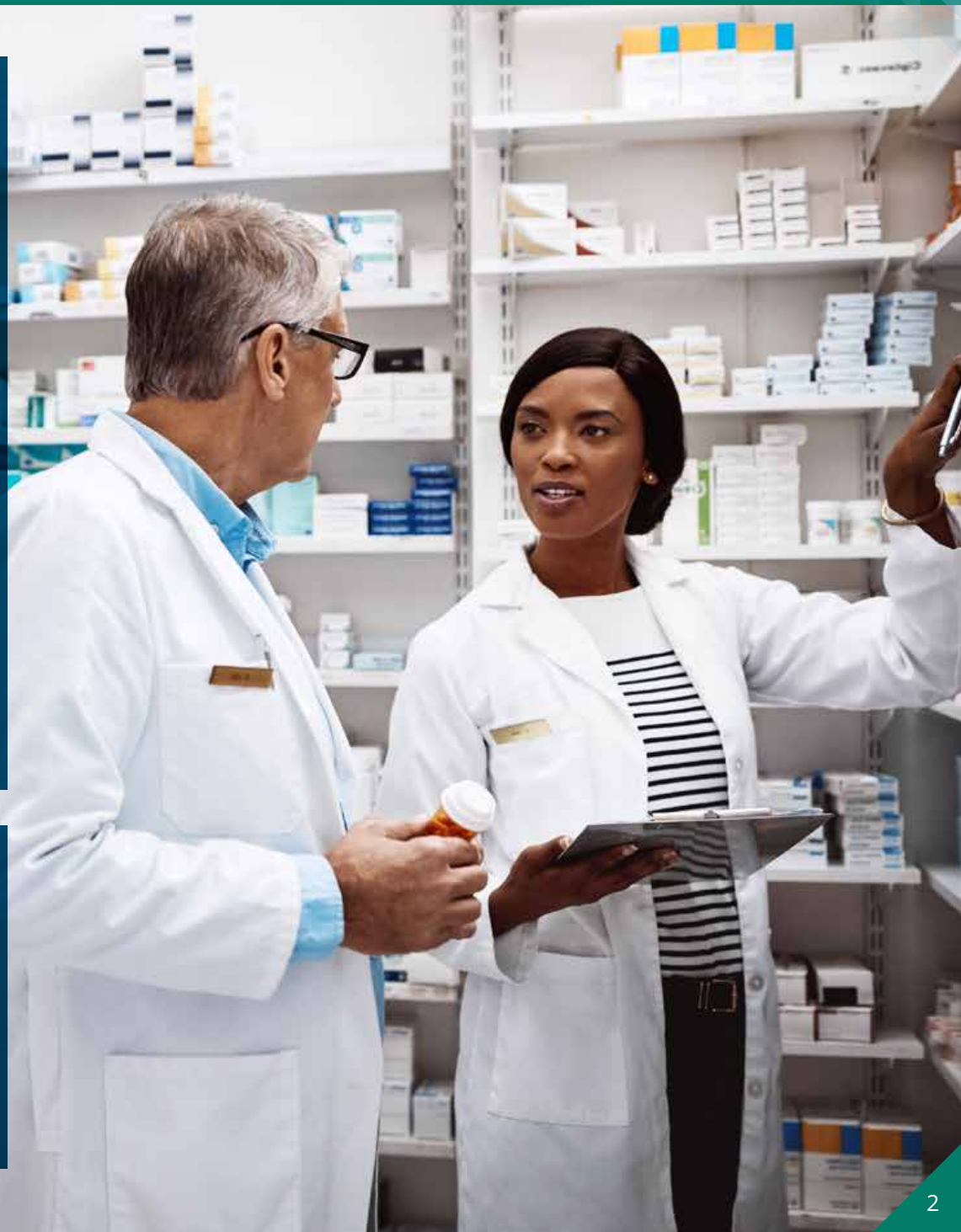
Compounding Pharmacy Compliance provides the latest in compounding regulatory guidance for ever-changing quality standards. This conference provides insights into best practices for processes, protocols and facility improvements, sterility and stability testing and data analysis through informative presentations, panel discussions, case studies and breakout discussions.

This year's agenda covers the latest in regulatory complexities, innovative technologies, and data analytics to address challenges in the compounding compliance space.

Attend your preferred track sessions and prepare for critical content tailored to your focus area, plus benefit from a more diverse speaking faculty and greater networking opportunities to expand your network and establish powerful partnerships.

2024 Experience June 18-19 | Boston, MA

- 2 Full Days of Content
- In-person Networking and Cocktail Receptions
- Recorded presentations from the event, available for 12 months on our Streamly digital platform – One whole year of conference content!



Conference Agenda

DAY ONE — TUESDAY, JUNE 18, 2024

*Please note all times are listed in EDT

7:30 AM	**Continental Breakfast and Registration**
8:50 AM	**Conference Chair's Opening Remarks**
9:00 AM	**Explore the Latest Revisions — Key Insights for the Updated USP Standards** • Discuss the latest on the recently implemented USP 797 and anticipated impact on sterile compounding • Updates on USP 795 and USP 800 • Analysis on how different states are adopting and implementing these guidance *Lauren Pearson, PharmD., MBA, Senior Scientist I, Personalized Medicines,* **US Pharmacopeia**
9:45 AM	**Get Inspection Ready** • Gain insight on how independent and national compounding companies can prepare for inspections • Preparing for on-site and remote inspections • Handling 483s once you are inspected *Ross Caputo, Ph.D., President,* **Eagle Analytical**
10:30 AM	**Networking and Refreshment Break**
11:00 AM	**Design a Robust Stability Program** • Understanding the desired or required regulatory standard for your organization • Building a stability program framework tailored around that regulatory standard • Differences amongst types of organizations — Hospitals, 503A, or 503B • Successful achievement of Beyond Use Dating or Expiration Dating *Masoud Rashidi, PharmD, Chief Compounding Pharmacist,* **Innovative Compounding Pharmacy** *Lisa L. McChesney-Harris, PhD, CEO, CSO & Founder,* **Prompt Praxis Laboratories LLC**
11:45 AM	**State Board Panel** Gain insights on regulatory perspectives from State board representatives regarding recent regulatory updates and what to know when you are licensed in multiple states. *Renee Barker, PharmD, BCSCP, Member,* **California State Board of Pharmacy**
12:30 PM	**Networking Luncheon**

CHOOSE FROM TWO TRACK OPTIONS

	503A	503B
1:30 PM	**An In-Depth Breakdown of Non-Sterile and Non-Hazardous Compounding Regulations** • Expectations of USP 795 for non-sterile compounding pharmacies • Which unsanitary conditions documents are applicable to 503As *Ted Toufas, Compounding Pharmacist,* **Acton Pharmacy** *Victor Hill, Director of Quality,* **Vios Compounding**	**Navigating Drug Shortages and Challenges in Current Supply Chain** With the recent supply chain issues and drug shortages, discuss: • How compounding pharmacies will be working to fill those gaps • What 503Bs are currently doing in the interim to mitigate shortages? • FDA considerations on bulk list revisions due to drug shortage • Navigating drug shortages due to quality issues from 503Bs
2:15 PM	**Navigating Drug Shortages, 503B Disruptions, and Vendor Qualifications** Explore the strategies in managing patient care amidst both drug shortages and 503B product scarcities, while gaining insights on the essential methodologies 503A compounding pharmacies can employ to effectively vet their supplies, mitigating potential risks within the supply chain. *Renee Barker, PharmD, BCSCP, Sterile Product Manager,* **Stanford Childrens Health** *Viral Jani, Director of Operations,* **Town & Country Compounding**	**Comprehensive Insights into 503B Quality Control** • Aseptic process manipulation • Shipping and validation for compounds • Qualifying vendors for API and critical components • 503 Bulk Lists *Trupti Sindhi, Manager Manufacturing Operations,* **QuVa Pharma** *Sophia Flores, Director of Manufacturing Operations,* **QuVa Pharma** *Jon Kallay, Senior Technology and Market Development Manager,* **Charles River Laboratories**
3:00 PM	**Afternoon Networking and Refreshment Break**	
3:30 PM	**503A Lab Testing, Quality Assurance, and Risk Mitigation** • Testing requirements for sterile and non-sterile compounding • Strategies for identifying and mitigating inconsistencies in 503A products *Jules D'Souza, 503A Quality Director,* **Empower Pharmacy** *Katrina Harper, Directory of Clinical Education,* **AIS Healthcare**	**Deep Dive on Regulatory Expectations for the Maturing 503B Industry** Engage in discussions on FDA 483 trends, the progression of the 503B market, and strategic measures to stay ahead of the curve in this industry.
4:15 PM	**Hospital Compounding — Challenges in Implementing USP 800 and NIOSH List** • Discuss the challenges surrounding USP 800 and the yet to be revised NIOSH list • Stay up to date with documentation requirements regarding environmental monitoring • Keeping up with environmental monitoring documentation requirements *Kathleen Kane, Assistant Director of Pharmacy, Compounding Integrity and Compounding Regulatory Compliance,* **UChicago Medicine**	**Session Spotlight — Biomerieux** Balancing increased production with quality assurance is a key challenge for Compounding Pharmacies. Discover how a top 503B outsourcing facility achieved this by prioritizing Quality Control Risk-Based Management, implementing reliable rapid sterility testing methods like solid phase cytometry for safe product release.

5:00 PM	**Networking Reception**

DAY TWO — WEDNESDAY, JUNE 19, 2024

**Please note all times are listed in EDT*

7:45 AM	**Continental Breakfast and Coffee Break**
8:50 AM	**Conference Chair's Review of Day One**
9:00 AM	**The Future of Veterinary Drug Compounding** Navigate the implications of GFI #256 (2023) on veterinary medicine and animal drug compounding from the bulk drug substance list. *Viral Jani, Director of Operations,* **Town & Country Compounding** *Donald Cantalino, Principal Owner,* **Vet Medics Pharmacy**
9:45 AM	**Selection and Validation of Automated and Semi-Automated Systems** • Gain insights on innovative solutions for full and semi- automictic robotics for syringe fillers, bag dosers • Using robotics to streamline cleanliness in clean room *Jay Bhaumik, CEO,* **Texas Star Pharmacy**
10:30 AM	**Networking and Refreshment Break**
11:00 AM	**Panel — FDA Regulatory Perspectives** • Discuss the proactive systems the FDA has in place • What is early protocols detection? • Explore the process of drug recall and risks posed to patient safety • Reclassification of hormone compounding **FDA Perspectives TBA**
11:45 AM	**Peptide Compounding — Regulatory Hurdles following FDA Reclassification** The FDA has reclassified multiple peptides to the category 2 bulks list due to recently identified safety risks. Join us as we discuss the anticipated implications of these reclassifications in the compounding space *Tenille Davis, Chief Advocacy Officer,* **Alliance for Pharmacy Compounding**
12:30 PM	**Networking Luncheon**

"I was delighted to hear the speakers at the conference. They were 100% open and willing to share their vast experiences with the group. It's great to hear from the FDA and others in a collaborative environment." *— Manager, Quality Assurance*

1:30 PM	**Advocating for Continued Patient Access to Compounded Medications** • Gain insights on the challenges with compounded medications not covered by insurance/Medicare • Explore key strategies in liaising with FDA and state boards
2:15 PM	**Hire, Train, and Retain — Addressing the Challenges of Staffing Shortages** • Training and retaining pharmacists and technicians • Finding qualified talent and following protocol to reduce medication errors • Understanding certification reports *Pallavi Badkar, VP of Operations,* **Medisourcerx** *Scott Shepard, Director of Home Infusion Service,* **Beth Israel Lahey Health** *Jay Bhaumik, CEO,* **Texas Star Pharmacy**
3:00 PM	**Chair's Closing Remarks and Close of Conference**

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Registration

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Venue Information

Revere Hotel Boston Common
200 Stuart St
Boston, MA 02116

ACCOMMODATIONS: For hotel room availability and direct booking links, please visit the conference website and select 'Plan Your Visit' below The Event Experience Tab. Rooms are limited and the discounted rate will expire in advance of the meeting, so please book early. All travel arrangements are subject to availability.

PLEASE NOTE: All hotel reservations for this conference should be booked directly with the hotel. Informa Connect does not partner with housing bureaus or third-party agencies for this event and none are authorized to call or contact you on our behalf.

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