Compounding Pharmacy Compliance

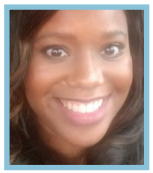
August 17-18, 2023 | Westin Copley Place | Boston, MA

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

Thought-provoking conversations led by expert speakers, including:

Lori Cantin, PharmD, MS
Branch Chief, Division of Compounding 2, Office of Compounding and Quality Compliance, **FDA**

Abby Roth
Owner/Microbiologist, **Pure Microbiology**



Katrina K. Harper
Director of Clinical Education, **AIS Healthcare**

David Short
Quality Vice President, **QuVaPharma Inc.**

Khang H. Pham, PharmD, BCSCP
Clinical Oncology Pharmacy Director, **Memorial Cancer Institute**

Ross Caputo, PhD
President & CEO, **Eagle Analytical**

Kristopher Le, PharmD
CEO & Principal Consultant, **Amicus**

Alison Gentile, PharmD
Director of Quality, **Pine Pharmaceuticals**

PLUS! Customize your learning experience through four thought-provoking tracks —
• **Intermediate Level** • **Senior Level** • **503A** • **503B**

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ABOUT THE EVENT

Compounding Pharmacy Compliance provides the latest in regulatory guidance for ever-changing quality standards. This conference provides insights into best practices for 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. Recorded and PDF presentations* from the event, available for 12 months on our Streamly digital platform — One whole year of conference content!

**Pending speaker permissions*

CONFERENCE AGENDA

DAY ONE — THURSDAY, AUGUST 17, 2023

**Please note all times are listed in EDT*

7:30 AM	**Continental Breakfast and Registration**
8:30 AM	**Conference Chair's Opening Remarks**
8:40 AM	**A Pharmacy Compounding Public Policy Update** Though specifically authorized in the federal Food, Drug & Cosmetic Act, some restrictions on compounded drug therapies threaten patient access and many of the restrictions are not rooted in science. During this session the following topics are explored: • USP's restrictions on beyond-use dates and batch sizes for compounded meds • FDA's threat to restrict compounded hormone therapy • As California Goes — Proposed regulations exceed national standards • The need for 503A compounders to prepare shortage drugs for urgent use • Proscriptions on Peptides and the reclassification of DTE • Proposed legislation to eliminate the MOU and implement 503A adverse event reporting *Scott Brunner, CEO,* **Alliance for Pharmacy Compounding**
9:25 AM	Panel Discussion **USP Revisions — Updates and Impacts of 795, 797, 800** • Nuances in chapter changes and the "why" behind the revisions • What effects will the new revisions have on 503A and 503B pharmacies? • Designated Person responsibilities • New implications for old compounds **PANELISTS:** *Melissa Stefko, Senior Director of Quality,* **The Flexpro Group** *Matt Martin, PharmD BCSCP, Director of Clinical Services,* **PCCA**
11:00 AM	**Costs of Compliance — Strategies to Ensure Compliance While Managing Rising Costs Due to Inflation** • Facility updates considering revisions — initial costs are heavy > Impacts for small companies and how to sustain substantial price increases > Challenges with supply chain **PANELISTS:** *Jason Mcguire, Vice President,* **FSS Operations** *A.J Day, Vice President of Clinical Services,* **PCCA**

11:45 AM	**What to Expect When You are Inspected** An FDA inspection can be a very stressful experience and can pose significant risk for pharmacies, compounding pharmacies and outsourcing facilities. That's why it is critical to be prepared. This session covers the nuts and bolts of an FDA inspection of a compounding facility and provide useful tips and tricks on navigating FDA's visit. The session also covers what happens after the inspection, including FDA's process and potential outcomes. Finally, the session discusses ways to remain proactive as opposed to reactive when it comes to FDA audits and inspections, in order to put your facility in the best position possible for a future FDA inspection. *Rachael Pontikes, Partner,* **Reed Smith LLP** *Emily Hussey, Partner,* **Reed Smith LLP**	
12:30 PM	**Networking Luncheon**	
	CHOOSE FROM TWO TRACK OPTIONS (A OR B)	
	A. INTERMEDIATE LEVEL	**B.** SENIOR LEVEL
1:30 PM	**Strategies to Optimize Facility Design and Engineering** • How to build facilities — What to consider if starting a facility from scratch; what should you consider? • Process workflows • Clean rooms — Importance of HVAC systems, airflow and pressure requirements *Sara Cheikelard, Architect,* **Wright McGraw Beyer Architects** *DJ Acker, Senior Mechanical Engineer,* **Controlled Environment Consulting**	**Hazardous Drug Handling and Risk Assessment** USP outlines a risk assessment process to consider the true nature of hazardous drugs. This session will start out by discussing USP 800 and then delve into topics such as: • Determining specific drugs for hazardous drug risk list • Selecting different categories for these risks • Exploring the possibility of standardized risk across the compounding space *Katrina K. Harper, Director of Clinical Education,* **AIS Healthcare** *Jessica Lee, PharmD, BCSCP, Pharmacy Compounding Supervisor,* **Memorial Cancer Institute** *John Daniel, PharmD, MHA, BCNP, BCSCP Clinical Pharmacist II,* **Christus Mother Frances Hospital**
2:20 PM	**Product Compliance — Lab Testing and Quality Assurance** From a raw powder to a final product, testing and quality assurance is continuously addresses the following topics • Most suitable testing methods • Process of sterility testing • Multi-incubations • Environmental monitoring requirements from state boards and FDA *Jonathan Kallay, Senior Technology and Market Development Manager,* **Microbial Solutions** *Alison Gentile, PharmD, Director of Quality,* **Pine Pharmaceuticals**	**Viable Sampling Ready** Establishing and maintaining the state of control within the sterile compounding area is essential in ensuring patients receive safe medications. Proper facility design, engineering controls and a robust contamination control strategy can only take you so far. Viable sampling is the only tool we have in determining the microbial state of control in the sterile compounding areas. This requires sterile compounding facilities to have a robust environmental monitoring program with detailed processes on the execution of sampling activities, results evaluation, data trending, targeted improvement metrics and effective corrective action preventative action plan documentation. To achieve the best quality outcome, the environmental monitoring program must go beyond the minimum standard requirements. This presentation will discuss the changes to USP <797> viable sampling requirements and provide insight into industry-accepted best practices. *Abby Roth, Owner/Microbiologist,* **Pure Microbiology**

3:05 PM	**Afternoon Networking and Refreshment Break**	
3:35 PM	**Best Practices and Safety Tips for Drug Compounding** • Differences in working with sterile vs. nonsterile drugs • Process and patient safety *Jeff Baird, Shareholder,* **Brown & Fortunato PC**	**Achieving Category 3 Beyond-Use Dating** Revisions to USP general chapter <797> on sterile compounding introduce new compounding categories in lieu of the currently official low, medium and high-risk categories. These new categories are the basis for establishing BUDs and consider the compounding environment, processing method, starting components and quality control test results of the finished CSP. This presentation will introduce the new compounding categories and focus on the requirements for achieving Category 3 BUDs including terminal sterilization, stability studies, testing and the increased frequency of personnel qualification and environmental monitoring. *Ross Caputo, PhD, President & CEO,* **Eagle Analytical**
4:20 PM	**Utilizing Data and Dashboards for Compounding Efficiency** Discuss using data to: • Identify issues with workload • Help finding appropriate staff • Potentially increase turnaround time	**Aseptic Compounding and Processing — Short and Long Term Approaches** • What are ideal solutions? • RABS units vs. Isolators > Cost vs. benefit > What are the short-term and long-term approaches? • Cleaning and disinfecting aseptic compounding rooms *David Short, Quality Vice President,* **QuVaPharma Inc.**
5:15 PM	**Networking Reception**	

DAY TWO — FRIDAY, AUGUST 18, 2023

Please note all times are listed in EDT

7:30 AM	**Continental Breakfast and Coffee**
8:30 AM	**Conference Chair Review of Day One**

CHOOSE FROM TWO TRACK OPTIONS (C OR D)

C. 503A

8:45 AM

Key Vendor Qualifications When Contracting with 503Bs

- Necessary vendor qualifications and certifications
- Issues with relying on the FDA for qualified vendor lists
- What to do when your vendor is shut down

Kathleen Kane, Pharm.D., BCSCP, Assistant Director of Pharmacy, Compounding Integrity and Compounding Regulatory Compliance, **UChicago Medicine**

9:40 AM

Hospital Perspective for Compounding Pharmacists

- Developing clean rooms in a hospital compounding setting — Initial costs vs. long term benefits?
- Creating business cases that encourage hospitals to implement technology management systems

Khang Pham, Clinical Oncology Pharmacy Director, **Memorial Cancer Institute**

Matt Martin, PharmD BCSCP, Director of Clinical Services, **PCCA**

D. 503B

8:45 AM

The Definition of Insanity — 503B Pitfalls that Just Keep Happening and How to Break the Cycle

The definition of insanity is doing the same thing over and over and expecting the same result. In the 10 years since DQSA was passed, the 503B industry has grown and evolved, but several pitfalls that have ultimately led to business and compliance failures remain present. This presentation will identify the mishaps commonly seen across the first decade of the 503b industry and provide successfully tested ways to overcome them.

Kristopher Le, PharmD, CEO & Principal Consultant, **Amicus**

9:40 AM

Regulatory Implementations Surrounding 503B Compounding

Considering current CGMP guidelines, there are many questions surrounding 503B compounding such as

- What are the specifics regarding the implementation of 503B compounding in a healthcare setting?
- What should we base these guidelines on?
- Insourcing vs. outsourcing

Varsha Gaitonde, Director Pharmacy Services, **QuVaPharma Inc.**

10:30 AM

Networking and Refreshment Break

11:00 AM

State Board Perspectives on Compounding Regulations

- Interstate Commerce — Harmonization of state boards for more streamlined compounding commerce
- Inspections process — How pharmacies can be better prepared

MODERATOR:

Susan Brichler Trujillo, Partner, **Quarles & Brady LLP**

Invite 3-4 State board representatives

11:45 AM

FDA Current Landscape — Priorities and Policies for Drug Compounding

- Addressing current compliance concerns
- New and updated regulatory standards and guidance for industry compounders
- Keeping up to date with information on qualified vendors

PANELISTS:

Hidee Molina, MS, Division Director, Division of Compounding 1, Office of Compounding Quality and Compliance, **FDA**

Lori Cantin, PharmD, MS Branch Chief, Division of Compounding 2, Office of Compounding Quality and Compliance, **FDA**

Dominic Markwordt, JD, Regulatory Counsel, Division of Compounding Policy and Outreach, Office of Compounding Quality and Compliance, **FDA**

12:30 PM

Networking Luncheon

1:30 PM	**Analysis of Varying Types of Management Systems** • Compounding: Different process perspectives from manual, semi-automatic and fully automatic — What are the benefits and challenges of each? > More discussion about robotics in this space on large and small scales • IV Workflow: Discussing the pros and cons of IV workflow systems and better utilizing information that is collected *Thomas Karakosta, PharmD., Vice President, Strategic Marketing,* **Consortiex**
2:20 PM	**Overcome Challenges Faced by Smaller Compounding Pharmacies** • Navigating challenges surrounding needing smaller quantities at a faster rate • Finding suppliers with the right volumes and timeliness • Regulatory scrutiny requiring more resources • Production capacity
3:10 PM	**Personnel Compliance and Training** • How are different organizations tackling training requirements? • Discussing the best resources in procuring the adequately trained personnel to run operations *Pallavi Badkar, Rph , M.S, BCSCP, Director Of Operations/Pharmacist in Charge,* **Medisource Rx** *Deborah McHugh, Senior Director Quality,* **Fagron Sterile Services**
4:00 PM	**Chair's Closing Remarks and Close of Conference**

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REGISTRATION

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Compounding Pharmacies/Academia/ Hospitals/Government	**$1499**	**$1799**
Solution & Service Providers/Law Firms	**$2499**	**$2799**

Venue Information

The Westin Copley Place Boston

10 Huntington Avenue
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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