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Compounding Pharmacy Compliance

MAY 17-18, 2018 • ALEXANDRIA, VA
EMBASSY SUITES BY HILTON ALEXANDRIA OLD TOWN

Understanding FDA Guidelines and Preparing for Audits

EXPERT FACULTY:

Ian Deveau, Ph.D., Branch Chief, Office of Manufacturing Quality, Office of Compliance, **CDER/FDA**

Matthew J. Buderer, R.Ph., FIACP, Vice President and Chief Compounding Pharmacist, **Buderer Drug Company**

Alexander Pytlarz, Owner/Director of Pharmacy, **The Compounding Center**

James Fink, Facilities Manager, Process Engineer, **Leiters Compounding**

Brian Michael Spencer, Director, Quality Assurance, **Chorus Eli Lilly and Company**

Rachael Pontikes, Partner, **Reed Smith LLP**

Lee Rosebush, Partner, **Baker & Hostetler LLP**

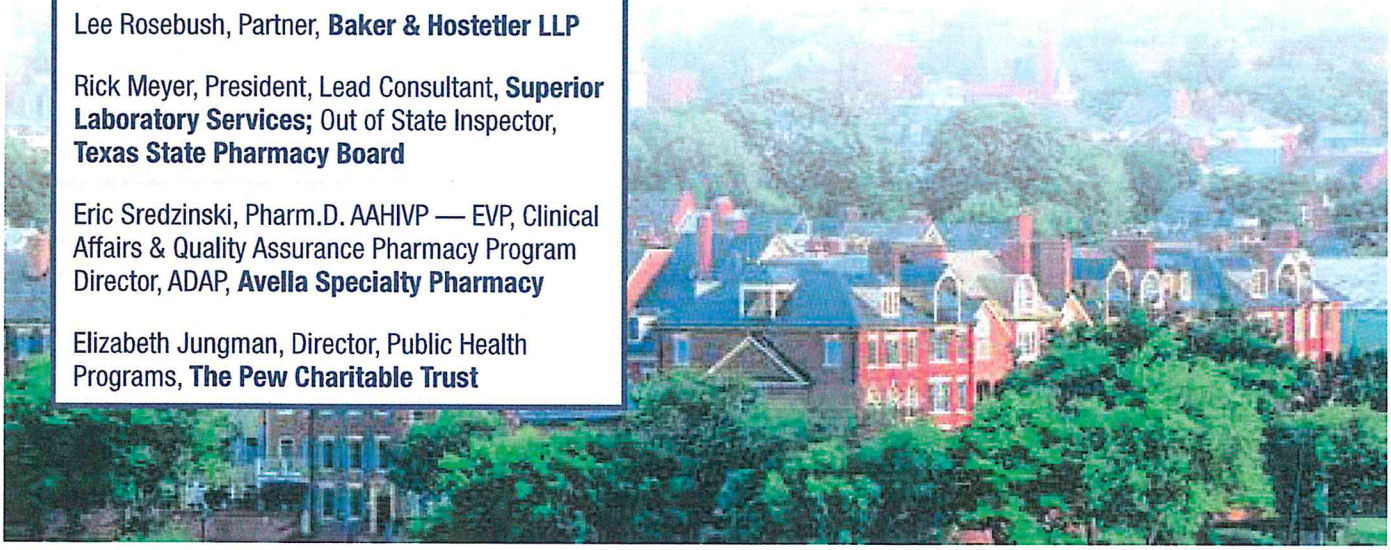
Rick Meyer, President, Lead Consultant, **Superior Laboratory Services;** Out of State Inspector, **Texas State Pharmacy Board**

Eric Sredzinski, Pharm.D. AAHIVP — EVP, Clinical Affairs & Quality Assurance Pharmacy Program Director, ADAP, **Avella Specialty Pharmacy**

Elizabeth Jungman, Director, Public Health Programs, **The Pew Charitable Trust**

In-depth Sessions and Discussions Include:

- Enhanced Enforcement Activity in the Compounding World
- Understanding and Conforming to USP 800 Guidelines and How They Relate to Changes with USP 797
- Customized Tracks for 503A and 503B — Learn About the Most Common Compliance Challenges and How to Avoid Them
- A Review of 483 Warning Letters and Observations and Effective Response Strategies
- How to Navigate Compliance with Both the FDA and the Pharmacy State Board
- Extended Session — How to Prepare for an Audit



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WHY THIS TIMELY CONFERENCE IS IMPORTANT TO YOU

After many incidents, such as the meningitis breakout in 2012, the FDA determined compounding pharmacies needed to be more closely monitored. New rules and regulations have come to fruition and compounding pharmacies are being held accountable to many of the same standards as the large drug manufacturing organizations. Many compounding pharmacies are not prepared for the complex FDA compliance requirements and there is confusion as to exactly what rules, regulations and guidelines must be followed. Our expert speaking faculty dissects various complexities regarding compliance with the FDA and pharmacy state boards, cGMP guidelines and standard operating procedures.

SESSIONS COVER:

- Expectations (Policy)
- Design (Operational design of sterile facilities)
- Operation (SOPs)
- Cleaning (Maintaining sterile facilities)
- Monitoring (Q/A)
- Audit planning and response (Regulatory)

TOP BENEFITS DELEGATES RECEIVE INCLUDE:

- Clarification of compliance with separate governing bodies (FDA or State Licensing Board)
- Insights on how to prepare for an FDA audit
- Compliance regulations and expectations for sterile compounding for 503B and 503A pharmacies
- Instructions on how to address 483 letters

WHO SHOULD ATTEND:

You will benefit from attending this event if you work within a compounding pharmacy and have the following titles:

Owner • Compliance • Policy & Regulatory • Pharmacy Operations
Pharmacy Services • Quality Assurance • Quality Control
Pharmacist • Counsel • Facilities Management

This conference will also benefit consultants and organizations that provide services to clean rooms, monitoring, facility design, data analysis, regulatory and policy consulting.

A GREAT PLACE TO MEET YOUR MARKET!

Maximize your access to decision-makers and align your brand with the life sciences industry's premier thought-leaders and industry innovators. CBI's custom sponsorship programs are designed to support your organization's overall business development and marketing initiatives through meaningful prospect and customer interactions, brand assertion campaigns and content-rich thought-leadership opportunities. Capitalize on the life sciences community's premier platform for peer-to-peer exchange, solution driven content and first-in-class networking opportunities.

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DAY ONE — THURSDAY, MAY 17, 2018

7:30 *Conference Registration and Continental Breakfast*

8:30 *Chairman's Welcome & Opening Remarks*
James Fink, Facilities Manager, Process Engineer, **Leiters Compounding**

Examine Policy and Compliance Expectations

8:45 **Sterile Compounding vs. Sterile Pharmaceutical Manufacturing and cGMPs**
- Similarities between sterile compounding and sterile pharmaceutical manufacturing
- USP <797> Pharmaceutical Compounding — Sterile Preparations
- FDA Guideline "Sanitary Conditions at Compounding Facilities" — What does this mean for your facility?

Brian Michael Spencer, Director, Quality Assurance, **Chorus Eli Lilly and Company**

9:30 **Enhanced Enforcement Activity in the Compounding World**
- Exploration of recent law enforcement activities by FDA and states
- Considerations of FDA when determining whether to pursue certain organizations
- Considerations of states when determining whether to pursue certain organizations
- Case studies

Rachael Pontikes, Partner, **Reed Smith LLP**

10:15 *Networking and Refreshment Break*

10:45 **Understanding and Conforming to USP 800 Guidelines and How They Relate to Changes with USP 797**
- Facility design considerations
- Movements in the facility by personnel
- Certification and environmental monitoring
- Cleanroom personnel PPE
- Determining contamination sources
- Continuous monitoring and why we need it

Rick Meyer, President, Lead Consultant, **Superior Laboratory Services;** *Out of State Inspector,* **Texas State Pharmacy Board**

11:30 **How to Navigate Compliance with Both The FDA and the Pharmacy State Board**

PANEL
- What happens when FDA guidelines are at odds with state board regulations
- How to best handle joint state board and FDA inspections
- Defining jurisdiction — When FDA and state board work together and when they don't

MODERATOR:
Elizabeth Jungman, Director, Public Health Programs, **The Pew Charitable Trusts**

PANELISTS:
Lee Rosebush, Partner, **Baker Hostetler**

Rick Meyer President, Lead Consultant, **Superior Laboratory Services,** *Out of State Inspector,* **Texas State Pharmacy Board**

Alexander Pytlarz, Owner/Director of Pharmacy, **The Compounding Center**

12:15 *Networking Luncheon*

Overcome Challenges in Design and Operation of Facilities — Learn about the most common challenges and how to remain compliant.

CHOOSE BETWEEN TWO TRACKS

TRACK 503A

CHAIRMAN:
Matthew J. Buderer, R.Ph., FIACP, Vice President and Chief Compounding Pharmacist, **Buderer Drug Company, Compounding Pharmacy**

1:15 **Re-Examining and Establishing Standard Operating Procedures for:**
- Labeling
- Packaging materials
- Documentation
- Personnel training and gowning
- Visual Inspection
- Cleaning program, frequency, technique
- Reacting to quality indicators (OOS, deviations, investigations, failures), CAPA, metrics, trends

Seth DePasquale, Co-Owner & Pharmacist in Charge, **BET Pharm**

TRACK 503B

CHAIRMAN:
Rick Meyer, President, Lead Consultant, **Superior Laboratory Services,** *Out of State Inspector,* **Texas State Pharmacy Board**

1:15 **Re-Examining and Establishing Standard Operating Procedures for:**
- Labeling
- Packaging materials
- Documentation
- Personnel
  - * enforcement
  - * vetting personnel

Andrew Stillufsen, General Council, **MegaAid Compounding Pharmacy**

2:00 **Steps for Effective Environmental Monitoring**
- Airflow, testing, HEPA filters
- Temperature/humidity monitoring
- Viable/non-viable surface and air testing
- Pressure differentials
- Aseptic processing and technique
- Media fills

James Fink, Facilities Manager, Process Engineer, **Leiters Compounding**

2:45 **Facility Design for Optimal Functionality and Compliance**
- Air quality
- Buffer areas
- Proper materials of construction
- Lab setup (sink placement, hoods etc.)
- Demarcation lines
- LAF, BSC hood qualification and maintenance

James Fink, Facilities Manager, Process Engineer, **Leiters Compounding**

3:30 *Networking and Refreshment Break*

4:00 **An Audit of a 503A**

CASE STUDY
- What my inspector was looking for
- How I conducted myself during the inspection
- How I responded to the 483s and warning letters

Matthew J. Buderer, R.Ph., FIACP, Vice President and Chief Compounding Pharmacist, **Buderer Drug Company, Compounding Pharmacy**

4:45 **An Examination of Different Facilities Methods for Quality Assurance and Quality Control**

PANEL
- Internal audits
- Laboratory testing & internal audits
- Validation beyond use state
- Sending sterile and non-sterile compounds to lab for potency
- Procedure and processes
- Testing for sterility
- Non-sterile to sterile compounds
- Know and understand USP 797 and 795

MODERATOR:
Alexander Pytlarz, Owner/Director of Pharmacy, **The Compounding Center**

PANELISTS:
Matthew J. Buderer, R.Ph., FIACP, Vice President and Chief Compounding Pharmacist, **Buderer Drug Company, Compounding Pharmacy**

Andrew Stillufsen, General Council, **MegaAid Compounding Pharmacy**

Seth DePasquale, Co-Owner & Pharmacist in Charge, **BET Pharm**

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Melissa Bainbridge, Science Director, **Edge Pharmacy Services**

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- Buffer areas
- Proper materials of construction
- Lab setup (sink placement, hoods etc.)
- Demarcation lines
- LAF, BSC hood qualification and maintenance

Melissa Bainbridge, Science Director, **Edge Pharmacy Services**

3:30 *Networking and Refreshment Break*

4:00 **An Audit of a 503B**

CASE STUDY
- What my inspector was looking for
- How I conducted myself during the inspection
- How I responded to the 483s and warning letters

Bret Snow, Regional Director of Pharmacy, **New England Life Care**

4:45 **An Examination of Different Facilities Methods for Quality Assurance and Quality Control**

PANEL
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- Laboratory testing and internal audits
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- Sending sterile and non-sterile compounds to lab for potency
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MODERATOR:
Brian M. Spencer, Director, Quality Assurance, **Chorus, Eli Lilly and Company**

PANELISTS:
Brett Snow, Regional Director of Pharmacy, **New England Life Care**

Sara Mott, QC Manager and Microbiologist, **Edge Pharmacy Services**

Eric Sredzinski, Pharm.D. AAHIVP – EVP, Clinical Affairs & Quality Assurance Pharmacy Program Director, ADAP, **Avella Specialty Pharmacy**

5:30 *Close of Day One*

NETWORKING, WINE AND CHEESE RECEPTION *immediately following the final session on day one*

DAY TWO — FRIDAY, MAY 18, 2018

8:00 *Continental Breakfast*

8:30 *Chairman's Review of Day One*
James Fink, Facilities Manager, Process Engineer, **Leiters Compounding**

Establish Regulatory and Audit Strategies

8:45 **FDA KEYNOTE**
Ian Deveau, Ph.D., Branch Chief, Office of Manufacturing Quality, Office of Compliance, **CDER/FDA**

9:30 **A Review of 483 Warning Letters and Observations — Effective Response Strategies**

- What steps can be taken to mitigate findings
- Go ahead — Review each point for clarification with the investigator
- Resist commenting and/or rejecting of observations
- Employ strategies to submit an effective response letter to the FDA findings

Lee Rosebush, Partner, **Baker & Hostetler LLP**

10:15 *Refreshment and Networking Break*

10:45 **EXTENDED SESSION**
Effectively Prepare for Your Upcoming Audit

The extended session on audit preparation outlines why it is critical to have a written plan maintained in a binder and easily accessible by responsible personnel. This plan should contain information on the person assigned to initially meet and accompany the FDA inspector, including name, phone number and location at site. It should also include a list of senior management officials' names, phone number and location on site. Learn more about creating this plan, including detailing the location for FDA inspector use during the inspection, and more.

- Ensure proper documentation and storage of records
- Invest time and designate accountable resources to implement and assess an effective compliance program
- Provide continuous training for personnel in relation to compliance requirements
- Engage in appropriate environmental controls and quality testing as required by the USP
- Foster a culture of compliance within your organization

Chris Wubbolt, President, **QACV Consulting**

12:00 *Chairman's Closing Remarks*
James Fink, Facilities Manager, Process Engineer, **Leiters Compounding**

12:15 *Close of Conference*

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John Kuchinski
PHONE 339-298-2112
EMAIL jkuchinski@cbinet.com

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REGISTRATION FEE:

	ADVANTAGE PRICING	Standard	Onsite
Conference	$999	$1299	$1399

Register by March 16, 2018 and SAVE $300. Fee includes continental breakfast, lunch, wine and cheese reception, refreshments and conference documentation. Credit Card (Visa, MC, AMEX, Discover) or checks accepted. Please make checks (in U.S. funds drawn on a U.S. bank) payable to: CBI. (No personal checks accepted.) PLEASE NOTE: All advertised discounts are taken from the full, Standard Rate.

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Alexandria, VA 22314
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Hotel Direct Line: 1-703-684-5900

ACCOMMODATIONS:

To receive CBI's special discounted hotel rate online or by phone, please go to:

- ***Online:*** www.cbinet.com/compounding
- ***Phone reservations:*** **1-800-445-8667 and mention CBI's Compounding Pharmacies**

Book Now! The Embassy Suites by Hilton Alexandria Old Town is accepting reservations on a space and rate availability basis. Rooms are limited, so please book early. All travel arrangements subject to availability.

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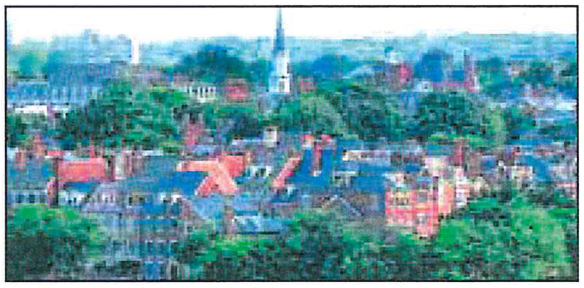

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