2ND ANNUAL
Compounding Pharmacy Compliance
June 19-20, 2019 • Silver Spring, MD
Sheraton Silver Spring Hotel
Interpret Changing Guidelines • Strengthen Quality Programs • Prepare for Inspections

REGISTER BY APRIL 12, 2019 AND SAVE $300!

ACPE® Credits Available
For Pharmacists
Pending Approval

COMPELLING AND TIMELY SESSIONS ON HIGH-IMPACT ISSUES:
• FDA Priorities and Enforcement Trends for 2019 and Beyond
• Understanding Bulk Substances Guidance and Nomination Process
• Strategies for Enhancing Quality Programs
• Techniques for Environmental Monitoring, Cleaning Validation and Stability Testing
• Navigating Compliance with State Boards and FDA
• Training Personnel for cGMP Compliance
• Preparing for and Responding to Facility Inspections

PLUS! CONCURRENT TRACKS FOR UNIQUE CHALLENGES FACED BY: 503A AND 503B PHARMACIES

Hear from 20+ expert thought leaders including:

FDA KEYNOTE
Ian Deveau, Ph.D.,
Branch Chief, Office of Manufacturing Quality,
Office of Compliance, CDER/FDA (invited)

John W.M. Claud,
Trial Attorney,
U.S. Department of Justice

Donnie Calhoun,
Chief Executive Officer,
Calhoun Wellness Pharmacy

Pat Stephens,
Former Owner,
Medi-Fare Drug

Seth DePasquale,
Owner and Pharmacist in Charge,
BET Pharm

Grace Breen,
Senior Vice President of Quality,
SCA Pharma

Sheri Zapadka,
Compliance Specialist,
State of Ohio Board of Pharmacy

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Supporting Media Partners:
Compounding pharmacies continue to grapple with increasingly intense scrutiny from state and federal regulators. IVT’s 2nd Annual Compounding Pharmacy Compliance provides an in-depth breakdown of these complex guidelines and an opportunity to discover strategies and solutions to enhance quality, ensure compliance and prepare for inspections. Join your peers in quality, compliance and regulatory affairs, in both general sessions and concurrent 503A and 503B tracks, to gain key takeaways and improve your quality program.

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

- Compliance
- Quality Assurance
- Quality Control
- Owner/President/CEO
- Pharmacy Operations
- Pharmacist in Charge
- General Counsel
- Legal
- Pharmacy Services
- Facilities Management
- Policy and Regulatory Affairs

This conference will also benefit consultants, law firms and technology vendors providing services to the above audience.

**WHAT THE INDUSTRY IS SAYING:**

“Opportunities for networking with colleagues in the [compounding] space are limited. Thank you for providing this forum for learning and interacting.”

- Director of Global Quality, SCA Pharmaceuticals

**CONFERENCE SPONSOR:**

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. For more information on how to position your company as a sponsor or exhibitor, contact Steve Markos at 339-298-2108 or email steven.markos@cbinet.com.
DAY ONE — WEDNESDAY, JUNE 19, 2019

7:15  Registration and Continental Breakfast

8:00  Chairman’s Welcome & Opening Remarks
      Jason McGuire, Vice President, Global Quality, Fagron

Deep Dive into the Regulations and Enforcement Trends in Compounding Today

8:15  FDA ADDRESS
      Examine FDA Priorities and Policies for Drug Compounding
      Gain insight on FDA’s perspective on oversight of drug compounding and recently published documents applicable for compounding facilities.
      • Sharpen understanding of key requirements from policies for implementing federal law on compounding
      • Outline FDA’s 2019 priorities and enhanced oversight of drug compounding
      • Consider ways to engage with FDA on compounding oversight, regulation and inspection
      Ian Deveau, Ph.D., Branch Chief, Office of Manufacturing Quality, Office of Compliance, CDER/FDA (invited)

9:00  Examine the Scope of Current Enforcement Trends in Compounding
      • Evaluate regulatory supervision of the compounding sector by state and federal regulators since the passage of the Drug Quality and Security Act
      • Consider FDA and DOJ priorities for enforcement within the compounding space
      • Investigate case studies of state and federal enforcement activities
      John W.M. Claud, Trial Attorney, U.S. Department of Justice

9:45  Networking and Refreshment Break

10:15 Review FDA Guidance on Use of Bulk Substances and Essential Copies
      Break down the revised draft guidance for use of bulk substances and compounding of essential copies.
      • Explore updated draft guidance for compounding of bulk drug substances
      • Break down the nomination and FDA evaluation process for 503A and 503B facilities
      • Assess the updated draft guidance for compounding of essential copies
      • Compare benefits of compounding bulk-to-sterile or sterile-to-sterile
      • Investigate most recent developments in related Endo/Par vs FDA litigation
      MODERATOR:
      Karla Palmer, Director, Hyman, Phelps, & McNamara

11:15 Enhance Compliance Programs with Improved Operating Procedures
      Build an Effective Quality Assurance/Quality Control Unit
      Develop a strong quality assurance and quality control program to ensure reliability and quality of compounded drugs.
      • Develop standard operating procedures
      • Build comprehensive and continued personnel training programs
      • Plan for internal audits
      Sara Mott, Quality Assurance Manager, Edge Pharmacy

12:00 Networking Luncheon

1:00  Considerations for Hazardous Drug Compounding in Sterile and Non-Sterile Facilities
      Evaluate how facility design and testing procedures differ for HD in sterile and non-sterile compounding facilities.
      • Breakdown USP <800> guidelines and testing protocols that should be followed for hazardous drug compounding
      • Compare sterile and non-sterile facility and containment designs
      • Distinguish 503A and 503B designs
      • Determine what procedures need to be monitored
      • Consider whether storage areas need special designs
      Rick Meyer, Out of State Inspector, Texas State Pharmacy Board, President, Lead Consultant, Superior Laboratory Services

1:45  Explore Techniques for Environmental Monitoring
      Evaluate different processes, procedures, required materials and equipment for Environmental Monitoring (EM) to ensure quality and control within the production environment.
      • Discuss various types of environmental monitoring to perform within your cleanroom
      • Utilize a risk-based approach to rationalize frequency and use of EM processes and procedures
      • Understand how results of EM should be interpreted and any actions to be taken if necessary
      Seth DePasquale, Owner and Pharmacist in Charge, BET Pharm

2:30 Networking and Refreshment Break
3:00-5:15 CHOOSE BETWEEN TWO TRACKS

TRACK 503A

CHAIRMAN: Donnie Calhoun, Chief Executive Officer, Calhoun Wellness Pharmacy

3:00 Mitigate Costs for Designing, Building and Maintaining a Compliant 503A Facility
Break down demands of designing and maintaining a compliant facility and explore strategies to minimize costs while maximizing quality.
- Learn about airflow, HVAC, temperature control, and humidity requirements
- Evaluate costs of redesigning facility and retraining personnel
- Explore solutions to reduce costs
  Donnie Calhoun, Chief Executive Officer, Calhoun Wellness Pharmacy

3:45 Exploring a Future in 503B — The Transition from 503A to 503B and cGMP Standards to Implement to Improve Your Facility
Examine the standards of 503B facilities and the demands of transitioning, along with aspects of cGMP to implement in your 503A facility now to stay ahead of industry trends.
- Understand quality driven practices and regulatory requirements of 503B facilities
- Consider implications, feasibility and complexities of transitioning and steps for registering with FDA
- Evaluate potential benefits of being a 503B facility
- Explore cGMP standards & principles to take home to your facility to enhance your quality management program even if you are not considering a transition
  Louis Diorio, Principal, LDT Health Solutions, Inc.

4:30 Compare Key Players — FDA and Pharmacy State Board Perspectives on Compliance
This panel breaks down the roles of the different entities that oversee compounding and their recommendations for navigating the landscape:
- Define jurisdiction – Learn when FDA and state boards work collaboratively and when they don’t
- Investigate differences in how USP <797> and <800> will be applied across states
- Learn what to expect for each type of inspection
- Explore issues of uniformity amongst inspectors
- Gauge how to navigate compliance with all entities
- Understand information sharing and complimentary action parameters

PANELISTS:
  Rick Meyer, Out of State Inspector, Texas State Pharmacy Board, President, Lead Consultant, Superior Laboratory Services
  Sheri Zapadka, Compliance Specialist, State of Ohio Board of Pharmacy

TRACK 503B

CHAIRMAN: Ed Zatta, President, RXQ Compounding

3:00 Evaluate the Importance of cGMP to the Safety of Compounded Drugs
Provide an overview of the six systems that the Good Manufacturing Practices control and outline how a compounding pharmacy complies with cGMP.
- Discuss the eight elements of a GMP Quality Management System
- Outline how cGMP applies to compounding
- Evaluate how FDA assesses the state of cGMP compliance once implemented
- Learn the basis of risk-based inspections and the five principles of audits
  Gary E. Ritchie, President, GER Compliance

3:45 Develop Personnel Training for GMP Compliance
Determine how to train staff to be GMP compliant and keep up with manufacturing standards.
- Understand how to develop a rigorous training program for keeping up with 21 CFR 211 manufacturing standards
- Establish procedures to educate staff on certification reports and environmental monitoring reports
- Restructure SOPs to sufficiently document testing data
  Nancy Costlow, Director of Operations, Atlas Pharmaceuticals

4:30 INTERACTIVE TABLE TALK
Address Real World GMP Compliance Challenges
This interactive discussion encourages participants to identify compliance challenges, re-examine standard operating procedures, and collaborate to cross-share learning and develop potential solutions.

MODERATORS:
  Melissa Bainbridge, Science Director QC, Edge Pharmacy
  Grace Breen, Senior Vice President of Quality, SCA Pharma
  Erik Tosh, Chairman and 2018 President, IACP, Vice President of Professional Services, Letco Medical

5:15 Close of Day One

Join Us for a Networking Wine and Cheese Reception at the Close of Day One
DAY TWO — THURSDAY, JUNE 20, 2019

8:30 Continental Breakfast

9:00 Chairman’s Review of Day One
Jason McGuire, Vice President, Global Quality, Fagron

9:15 Discuss Techniques for Cleaning Validation
Explore the regulatory requirements regarding cleaning of facilities, equipment and utensils and the steps for executing proper cleaning validation protocols.
- Understand industry standards pertaining to cleaning validation
- Select a vendor to partner with in developing and executing validation protocol
- Learn how to maintain a validated state and monitor your procedures
Melissa Stefko, Vice President of Quality Assurance, Wells Pharmacy Network

10:00 Stability Testing and Beyond-Use-Dates — Ensuring the Quality of Sterile and Non-Sterile Compounded Preparations
Understand the requirement for stability testing and its role in determining shelf life.
- Key elements to consider in establishing a stability program
- Develop a risk-based approach to determining beyond-use-dates in compliance with revised GMP guidance
- Establishing beyond use dates, expiry dates and “in-use times”
- Stability testing for sterile and non-sterile compounded preparations
Gary E. Ritchie, President, GER Compliance

10:45 Networking and Refreshment Break

Prepare for Facility Inspections and Respond to 483s

11:15 EXTENDED SESSION
Prepare for Your Upcoming Inspection
This extended session outlines the most critical steps to take in developing and executing a comprehensive inspection preparation plan.
- Explore ways to achieve rapid inspection readiness
- Ensure proper documentation of standard operating procedures and records
- Learn how to perform self-audits of commonly requested documents
- Explore the value of mock inspections in training pharmacy staff
- Explore trends in FDA inspection and post-inspection enforcement efforts
Robert W. Stannard, Esq., Partner, Bendin Sumrall & Ladner
Stephen T. Snow, Esq., Partner, Bendin Sumrall & Ladner

1:15 A Review of 483s and Warning Letters — Effective Response Strategies
Hear about trends in recent 483s and warning letters and outline best practices for responding properly and efficiently.
- Explore an overview of historical FDA 483s and common observations
- Hear case studies of responses to warning letters
- Review good practices for engaging with inspectors
- Develop strategies to submit effective responses to inspector findings
Willis Triplett, Principal, Comply797

2:00 FINAL TAKEAWAYS AND CLOSING DISCUSSION
Why We Compound — Advocating for Patients and the Industry
With its everchanging regulations, the compounding landscape can be a confusing, fast-paced place to exist. However, it is imperative that we remember why compounding exists: to give the best possible care for patients. This session brings the focus back to the roots of compounding, the importance of the industry and how we can continue to fight for patients and the industry.
- Address impact of regulatory challenges on patient access to compounded drugs
- Share success stories of compounding along with areas where the industry falls short in providing for patients
- Recognize key policymakers relevant to compounding
- Identify important objectives and channels available for community with policymakers
Lisa D. Ashworth, Compounding Specialist and Clinical Pharmacist, Children’s Healthcare System of Texas
Jake Olson, President/Chief Executive Officer, Skywalk Pharmacy

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Compounding Pharmacy Compliance

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