IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY Presents

ACPE Credits for Pharmacists Pending

Compounding Pharmacy Compliance WEST

Navigate the Changing Regulatory Landscape and Enhance Quality Programs

SEPTEMBER 17-18, 2019 • SAN DIEGO, CA

DAY ONE SEPTEMBER 17, 2019

7:00	Main Conference Registration and Continental Breakfast
8:00	Chairperson's welcome
8:15	FDA ADDRESS Analyze FDA Priorities and Policies for Oversight of Drug Compounding
9:00	PANEL * Review FDA Guidance on Use of Bulk Substances and Essential Copies
10:00	Networking and Refreshment Break
10:30	Risk Mitigation and Maintenance of Sanitary Conditions in Compounding Facilities
11:15	Discuss Best Practices for Monitoring and Testing Procedures in Clean Rooms
12:00	Networking Luncheon
1:05	**Attendees Choose Between Three Concurrent Tracks**

A. 503A: Understand and Incorporate USP Standards into Compounding Practices	B. 503B: Break Down Revised GMP Guidelines	C. Hospital/Health-System: Mitigate the Impact of Drug Shortages on Inhouse vs. Outsourced Compounding

1:50	**Attendees Choose Between Three Concurrent Tracks**

D. 503A: Strategies to Design, Build and Equip a Compliant Compounding Pharmacy	E. 503B: Develop Personnel Training for GMP Compliance	F. Hospital/Health-System: Build Comprehensive and Consistent Educational Programs for USP and cGMP Adherence Across Health Systems

2:35	Networking and Refreshment Break
3:05	**Attendees Choose Between Three Concurrent Tracks**

G. 503A: Consider a Future in 503B-- The Transition from 503A to 503B and Practices to Adopt to Improve Your Facility	H. 503B: Develop a Comprehensive CAPA Program and Improve Change Control Processes	I. Hospital/Health-System: Moving Towards Safer, Streamlined Processes through Automated IV Compounding

3:50	**Attendees Choose Between Three Concurrent Tracks**

J. 503A: Inspection Preparation and Response– What to Expect in a State Board Inspection of a 503A Pharmacy	K. 503B: Inspection Preparation and Response - What to Expect in a State Board Inspection of a 503A Pharmacy	L. Hospital/Health-System: Inspection Preparation and Response – What to Expect in a Joint Commission Inspection of a Hospital/Health-System Pharmacy

4:50	Close of Day One

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DAY TWO SEPTEMBER 18, 2019

8:00	COMPOUNDERS CLOSED-DOOR BREAKFAST AND DISCUSSION
8:45	Chairperson's Review of Day One
9:15	**Attendees Choose Between Three Concurrent Tracks**

M. PANEL* Compare Key Players -- FDA, Industry and Pharmacy State Board Perspectives on Compliance

N. ROUND TABLES * Address Real World GMP Compliance Challenges

10:15	Networking and Refreshment Break
10:45	**ROUND TABLES** | USP <800> and <797> Readiness Roundtables
11:45	Cleaning Validation
1:30	Stability Testing and Beyond Use Dating
2:15	A Review of 483 Warning Letters and Observations – Effective Response Strategies
3:00	Close of Conference

As FDA hones in its focus on quality of compounding drugs, compounding pharmacies must adjust their operations to comply with changing quality standards and prepare for increased inspections. **IVT's 2nd Annual Compounding Pharmacy Compliance West** provides a platform for industry leaders to come together, interpret these new guidelines, share best practices and collaborate to ensure continued quality. Through general sessions and three concurrent tracks serving the unique needs of 503A, 503B, and hospital and health-system compounding pharmacies, our expert multi-stakeholder faculty will lead engaging and interactive discussions on the most relevant and timely topics. Join your peers to address key concerns including USP compliance, CGMP adherence, compounding from bulk substances and inspection preparation at this must-attend industry event.

NEW FOR 2019:

- 3 Tracks Serving The Unique Needs Of 503A, 503B And Hospital And Health-System Compounding Pharmacies
- Usp <800> And <797> Readiness Roundtables
- **COMPOUNDERS CLOSED-DOOR BREAKFAST AND DISCUSSION**
  This interactive discussion provides an opportunity for compounding pharmacists to convene in a private session and discuss key takeaways and practices gained at the program thus far to ensure continued compliance. Participants are encouraged to bring remaining questions to this session and benefit from gaining peer-to-peer perspectives from compounders of various sizes and specialties.