Compounding Quality Center of Excellence 2025 Hybrid Conference

Meeting Patient Needs for Quality, Safety, Integrity and Access

August 27–28, 2025

VIRTUAL PRE-CONFERENCE: MONDAY, AUGUST 25, 2025

Time	Session	Description
2:00 PM – 5:00 PM ET	**Facility Design and Preparation**	Discover the essential facility design elements to control environmental parameters, such as temperature, humidity and pressure. This presentation will be followed by a panel of outsourcing facilities to share challenges and considerations on setting up their facility and quality systems.

DAY ONE: WEDNESDAY, AUGUST 27, 2025

Time	Session	Description
9:00 AM – 10:30 AM ET	**Meeting Patient Needs Through the Years**	Compounders have evolved to meet the changing needs of patients and providers. Explore how this evolution has positioned compounders in today's broader healthcare landscape.
10:30 AM – 10:45 AM ET	**Break**	
10:45 AM – 11:45 AM ET	**Customer Perspective: Initial Evaluation of an Outsourcing Facility**	Understand the process of how customers evaluate outsourcing facilities and the requirements of various accreditation organizations. Learn best practice approaches from entities that evaluate outsourcing facilities as potential suppliers.
11:45 AM – 1:00 PM ET	**Lunch Break**	
1:00 PM – 2:00 PM ET	**Drug Shortage Mitigation by Outsourcing Facilities**	Explore how outsourcing facilities can help mitigate drug shortages. Discuss best practices, challenges and industry gaps.
2:00 PM – 3:00 PM ET	**Networking Break**	

DAY ONE: WEDNESDAY, AUGUST 27, 2025

Time	Session	Description
Day One Concurrent Sessions (1a–1c)		
Session 1a **3:00 PM – 3:50 PM ET**	**Customer Perspective: Ongoing Evaluation of an Outsourcing Facility**	Understand strategies that potential customers employ for ongoing evaluation of an outsourcing facility utilizing routine reviews, quarterly quality reports and periodic onsite evaluations.
Session 1b **3:00 PM – 3:50 PM ET**	**End-to-End Production of a Drug in Shortage by Outsourcing Facilities**	Learn what it takes to safely and successfully develop and launch a drug in shortage as an outsourcing facility.
Session 1c **3:00 PM – 3:50 PM ET**	**Stability Studies and Validation**	Explore recent examples of inspection deficiencies found at outsourcing facilities and testing laboratories under 21 CFR Part 211.166. Learn the do's and don'ts when using a stability program either in-house or at a contract laboratory.
3:50 PM – 4:00 PM ET	**Break**	
Day One Concurrent Sessions (2a–2c)		
Session 2a **4:00 PM – 4:50 PM ET**	**Visual Inspection**	Learn how to take your visual inspection practices to the next level.
Session 2c **4:00 PM – 4:50 PM ET**	**Media Fills**	Explore the fundamentals of media fills and how to apply them.
4:50 PM – 5:00 PM ET	**Break**	
In-person Exclusive **5:00 PM – 6:00 PM ET**	**Emerging Topics in Compounding**	Learn about emerging topics in compounding from FDA experts. Get your questions answered by FDA panelists.

DAY TWO: THURSDAY, AUGUST 28, 2025

Time	Session	Description
9:00 AM – 10:00 AM ET	**Establishing Standardized Formulations**	Learn about standardizing ready-to-administer compounded drugs produced by outsourcing facilities to create additional redundancies for optimal hospital support.
10:00 AM – 10:10 AM ET	**Break**	
Day Two Concurrent Sessions (3a–3c)		
Session 3a **10:10 AM – 11:00 AM ET**	**Drug Enforcement Administration (DEA) Quota Essentials for Outsourcing Facilities**	Understand the regulations for DEA licensure and quotas as they apply to outsourcing facilities. Delve into the complexities of managing DEA quotas as an outsourcing facility.
Session 3b **10:10 AM – 11:00 AM ET**	**Meeting the Needs of Special Populations**	Explore the unique needs of special populations and how outsourcing facilities can meet them by collaborating with industry, providers and families.
Session 3c **10:10 AM – 11:00 AM ET**	**Immediate-use Syringes and the Risks of Extended Use**	Learn why syringes not specifically designed for long-term storage can pose risks when stored for extended periods, compared to those intended for long-term use.
11:00 AM – 11:10 AM ET	**Break**	
Day Two Concurrent Sessions (4a–4c)		
Session 4a **11:10 AM – 12:00 PM ET**	**USP General Chapters and Outsourcing Facilities**	Learn how to apply the four critical U.S. Pharmacopeia (USP) General Chapters that define the microbiological testing landscape — <60>, <61>, <62> and <71> — in routine testing, understand how each chapter connects to risk management and patient safety and learn how to select a microbiology laboratory partner.
Session 4b **11:10 AM – 12:00 PM ET**	**Cleanroom Gowning: 5 Common Mistakes and How to Address Them**	Discover the most frequent mistakes made during cleanroom gowning procedures, which are critical for maintaining sterile environments in ISO 5 and ISO 7 cleanrooms, and how to address them. Understand the importance of discipline, training and adherence to proper procedures to ensure consistent cleanroom gowning integrity.

DAY TWO: THURSDAY, AUGUST 28, 2025

Time	Session	Description
Session 4c **11:10 AM – 12:00 PM ET**	**Introduction to Water Systems**	Learn the critical attributes and product impact of maintaining a water facility in-house.
12:00 PM – 1:00 PM ET	**Lunch Break**	
1:00 PM – 2:00 PM ET	**Deep Dive into 483 Observations**	Explore Form FDA 483 observations to understand common issues and potential pitfalls.
2:00 PM – 3:00 PM ET	**Wholesaling Guidance Highlights**	Understand FDA's draft guidance on the wholesaling prohibition under section 503B, including FDA's proposed interpretation of key terms and the application of the provision using examples involving sales, transfers, third-parties and dispensing.
3:00 PM – 3:15 PM ET	**Break**	
3:15 PM – 4:30 PM ET	**Meeting Patient Needs for the Future**	Learn from a variety of experts about the evolving needs of outsourcing facility customers and the patients they serve. Explore emerging trends, regulatory considerations and key product demands shaping the future of compounded drugs. Gain valuable perspectives on how outsourcing facilities can better serve a range of healthcare needs in an ever-changing landscape.