Compounding Quality Center of Excellence 2024 Hybrid Conference

Learning and Collaborating: Driving Toward the Future of Quality

August 21–23, 2024

VIRTUAL PRE-CONFERENCE: MONDAY, AUGUST 19, 2024

Time	Session	Description
2:00 PM – 5:00 PM ET	Developing a New Outsourcing Facility: Lessons Learned	Learn from established outsourcing facility leaders about the challenges of forming a new outsourcing facility and keys for success. Perspectives will include a hospital system-owned outsourcing facility, a 503A pharmacy that transitioned to an outsourcing facility, an outsourcing facility developed within a pharmaceutical company, and an outsourcing facility formed as a start-up. A panel discussion will share experiences interacting with newly formed outsourcing facilities.

DAY ONE: WEDNESDAY, AUGUST 21, 2024

Time	Session	Description
1:00 PM – 1:15 PM ET	Welcome and Opening Remarks	
1:15 PM – 2:30 PM ET	Opening Plenary: Learning and Growth: Successes and Challenges of a Developing Industry	Explore the evolution of the outsourcing facility industry, including quality and factors influencing long-term viability.
2:30 PM – 3:30 PM ET	The Business Case for Quality and Resilience	Discover perspectives from outsourcing facilities and customers on the benefits of investing in quality and resilience.
3:30 PM – 3:45 PM ET	**Break**	

DAY ONE: WEDNESDAY, AUGUST 21, 2024 (continued)

Time	Session	Description
Day One Concurrent Sessions (1a–1d)		
Session 1a **3:45 PM – 4:45 PM ET**	Risk Assessment in Aseptic Processing	Learn risk assessment tools for assessing aseptic processing operations that leverage technologies to increase sterility assurance.
Session 1b **3:45 PM – 4:45 PM ET**	Investigating Environmental Monitoring Excursions	Analyze an investigation of an environmental monitoring excursion highlighting critical aspects, such as microbiology and risk evaluation of the facility.
Session 1c **3:45 PM – 4:45 PM ET**	Visual Inspection	Learn the importance of visual inspection and review basic concepts illustrated with case studies.
Session 1d **3:45 PM – 4:45 PM ET**	Testing: Industry Perspectives	Explore the advantages and disadvantages of utilizing internal vs. external testing. Examine processes for handling out-of-specification and out-of-trend results.
4:45 PM – 5:00 PM ET	**Break**	
In-person Exclusive **5:00 PM – 6:00 PM ET**	Top 483 Observations	Learn about observations frequently encountered in FDA inspections of outsourcing facilities.

DAY TWO: THURSDAY, AUGUST 22, 2024

Time	Session	Description
9:00 AM – 9:15 AM ET	Day 2 Welcome	
9:15 AM – 10:15 AM ET	Pediatric Considerations for Outsourcing Facilities	Discover how outsourcing facilities can be well positioned to meet many of the unique needs of children's hospitals. Learn how collaboration can ensure pediatric access, quality and safety.
10:15 AM - 11:15 AM ET	Assessing Quality	Gain exposure to strategies and cases studies for internally assessing quality and the state of control within the framework of section 503B and CGMP.
11:15 AM - 12:45 PM ET	**Lunch Break**	

DAY TWO: THURSDAY, AUGUST 22, 2024 (continued)

Time	Session	Description
Day Two Concurrent Sessions (2a–2d)		
Session 2a **12:45 PM – 1:45 PM ET**	Reframing Perspectives through CGMP Training	Gain understanding about how the training provided in pharmacy and other industries may not align with CGMP thinking. Learn how to align the thinking across the disciplines.
Session 2b **12:45 PM – 1:45 PM ET**	Data Integrity	Examine the expectation that all data related to drug production is to be reliable and accurate to ensure the safety, efficacy, and quality of drugs.
Session 2c **12:45 PM – 1:45 PM ET**	Navigating State Laws and Regulations	Learn about variable state laws and regulations. Get updates on the latest potential state requirements and trends as they pertain to outsourcing facilities.
Session 2d **12:45 PM – 1:45 PM ET**	Cross-Contamination Concerns in Production	Review practices for preventing cross-contamination in facilities. Consider concepts of employee safety, handling of various hazardous drug substances, and ensuring production lines mitigate crossover through appropriate deactivation, cleaning, and residue monitoring.
1:45 PM – 2:00 PM ET	**Break**	
Day Two Concurrent Sessions (3a–3b)		
Session 3a **2:00 PM – 3:00 PM ET**	Strategies for Developing an Effective Training Program	Learn strategies for developing an effective training program, such as implementation, methodologies, retraining, and connecting initial training to daily work activities.
Session 3b **2:00 PM – 3:00 PM ET**	Not Just Blowing Smoke: Why Smoke Studies are Critical	Explore the concept of airflow visualization and critical considerations to ensure an optimum smoke study. Examine standards, regulations, and guidance for airflow visualization, as well as examples demonstrating poor airflow and good airflow.

DAY TWO: THURSDAY, AUGUST 22, 2024 (continued)

Time	Session	Description
	Day Two Concurrent Sessions (3c–d) continued)	
Session 3c **2:00 PM – 3:00 PM ET**	The Role of the Pharmacist in the Realm of Outsourcing Facilities	Explore the role of the pharmacist in the context of outsourcing facilities and health system pharmacies that interact with outsourcing facilities.
Session 3d **2:00 PM – 3:00 PM ET**	Automation: Environment and Facility Considerations	Discover the advantages of incorporating Restrictive Access Barrier (RABs) into aseptic processing operations and when it makes sense to incorporate RABs into a facility. Consider facility design, environmental controls, and aseptic practices considerations. Includes examples of active aseptic operations with RABs.
3:00 PM – 3:30 PM ET	**Break**	
In-person Exclusive **3:30 PM – 5:00 PM ET**	FDA News and Q&A	Get updates from FDA on recent developments in compounding relevant to outsourcing facilities, followed by an open question and answer session with the audience.

DAY THREE: FRIDAY, AUGUST 23, 2024

Time	Session	Description
9:00 AM – 10:00 AM ET	Welcome and Impact of Compliance on Product and Patient	Explore the differences and interplay between quality and compliance. Learn from examples that illustrate the impact of non-compliance on the product and patient.
10:00 AM – 11:00 AM ET	Excipient Quality	Get an overview of excipients within the context of sterile compounding and understand the importance of excipient quality.
11:00 AM – 11:15 AM ET	**Break**	
11:15 AM – 12:00 PM ET	Sustaining and Building the Future of Quality Across Networks	Learn about tools available to outsourcing facilities and how to leverage knowledge and create partnerships for the future.
12:00 PM – 12:30 PM ET	Closing Remarks	