Compounding Quality Center of Excellence 2023 Virtual Conference

Ten Years as a Regulated Outsourcing Facility Industry: Addressing Challenges to Improve Patient Care

September 11-13, 2023

PRE-CONFERENCE: MONDAY, SEPTEMBER 11, 2023

Time	Session	Description
2:00-5:00 PM ET	Quality Essentials	FDA presentations followed by questions and discussion that will explore fundamental concepts in quality, including Quality Unit formation and operation, as well as an overview of quality management systems, quality risk management, and their integration into firms' practices.

DAY ONE: TUESDAY, SEPTEMBER 12, 2023

Time	Session	Description
11:00-11:15 AM ET	Welcome & Opening Remarks	
11:15 AM-12:30 PM ET	Opening Plenary: Ten Years of Regulated Outsourcing Facilities: A Decade of Progress, But More to Do	Presentation on progress made in the outsourcing facility industry over the past ten years as well as challenges that remain within the industry, with an emphasis on quality. Panel with FDA and industry representatives will follow.
12:30-12:45 PM ET	***Break***	
12:45-2:00 PM ET	Guidances: FDA Updates and Impact of Stakeholder Input on FDA Guidance Development	Updates on FDA guidances as well as an overview of the guidance development process and how stakeholder input impacts the development of guidances.
2:00-2:15 PM ET	***Break***	
2:15-3:15 PM ET	Stakeholder Perspective: 503Bs as Partners to Providers: Benefits and Challenges	Panel discussion that will explore the benefits and challenges of utilizing 503Bs from both the industry and customer perspectives.
3:15-3:45 PM ET	***Break***	

3:45-4:45 PM ET	SESSION A: Quality Throughout the Supply Chain	Roundtable discussion on maintaining quality throughout the supply chain. The panel will offer both the supplier perspective, from raw material acquisition through production, and the customer perspective.
	(Concurrent Sessions)	
	SESSION B: Shortages and Lessons Learned	Panel to discuss lessons learned from recent shortages during COVID and other acute illness outbreaks and how outsourcing facilities might be utilized to bridge gaps for both short-term and long-term drug shortages.
4:45-4:50 PM ET	***Break***	
4:50-5:35 PM ET	Managing State Regulatory Challenges	Presentation to discuss recommendations for navigating varied state regulatory requirements for outsourcing facilities and explore challenges from states' perspectives in harmonizing regulatory requirements.

DAY TWO: WEDNESDAY, SEPTEMBER 13, 2023

Time	Session	Description
11:00 AM-12:00 PM ET	Stakeholder Perspective: Purchasing and Forecasting: How it Works	Presentation to discuss methods used for demand forecasting and the importance of transparency between purchasers and suppliers. Panel discussion to follow.
12:00-12:30 PM ET	***Break***	
12:30-1:30 PM ET	SESSION A: Product Complaints and Investigations	Presentation that will include how to address product complaints as well as how to design and conduct robust investigations.
	(Concurrent Sessions)	
	SESSION B: Automation and Validation	Presentation that will introduce the benefits of incorporating automation and outline practices for validating equipment when integrating automation into processes.
1:30-2:00 PM ET	***Break***	

2:00-3:00 PM ET	Questions and Discussion With FDA	FDA panel that will discuss how companies may receive responses from FDA to address their questions and issues, and the ways in which FDA is able to respond. A large portion of the session will be reserved as an open question-and-answer period with conference participants.
3:00-3:30 PM ET	***Break***	
3:30-4:30 PM ET	Closing Plenary: The Next Ten Years	Panel that will provide both industry and stakeholder perspectives on goals and visions for industry in the next ten years.
4:30-4:45 PM ET	Closing Remarks	