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	Speakers
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.	• Ian Deveau (FDA) • Jose Lopez (FDA) • June Page (FDA)

DAY ONE: TUESDAY, SEPTEMBER 12, 2023

Time	Session	Description	Speakers
11:00-11:15 AM ET	Welcome & Opening Remarks		• Commissioner Dr. Robert Califf (FDA)
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.	*Presenter* • Eric Kastango (Compounding Quality and Patient Safety Consultant) *Moderator* • Allan Coukell (Civica Rx) *Panelists* • Ian Deveau (FDA) • Elizabeth Miller (FDA) • Kathleen Anderson (FDA) • Michael Wascovich (Ascension Health)

			• Deborah McHugh (Fagron Sterile Services) • Pat Stephens (Stephens GMP Consulting) • Travis Leeah (QuVa Pharma)
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.	• Gabrielle Cosel (FDA) • Rechelle Buford (FDA) • Dominic Markwordt (FDA)
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.	*Moderator* • Michael Ganio (ASHP) *Panelists* • Richard Montgomery (AdventHealth) • Carolyn Liptak (Vizient, Inc.) • Adam Ewald (Mayo Clinic) • Aimee Melling (The Ritedose Corporation) • Hale Dimetry (PQ Pharmacy) • Iván Martínez (Leiters)
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.	*Moderator* • Francis Godwin (FDA) *Panelists* • Ian Deveau (FDA) • Gretchen Brummel (Vizient, Inc.) • Lisa Hanlon (Pennsylvania State University) • Robert Nickell (Nubratori)

			• Scott Luce (SCA Pharma)
	(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.	*Moderator* • Gail Bormel (FDA) *Panelists* • Gabrielle Cosel (FDA) • Joe Bagan (STAQ Pharma) • Constance Long (Hikma Pharmaceuticals) • Lee Rosebush (Outsourcing Facilities Association (OFA)) • Phanesh Koneru (Exela Pharma Sciences)
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.	• Gregg Jones (National Association of Boards of Pharmacy (NABP))

DAY TWO: WEDNESDAY, SEPTEMBER 13, 2023

Time	Session	Description	Speakers
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.	*Presenter/Panelist* • Kevin Hansen (Premier, Inc.) *Moderator* • Noah Leja (Michigan Medicine) *Panelists* • Garrett Eggers (Cleveland Clinic) • Emily Meyer (Advocate Health)

			• Russ Funk (Banner Health)
12:00-12:30 PM ET	***Break***		
12:30-1:45 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.	• Brandon Heitmeier (FDA) • Mina Ahmadi (FDA) • Shannon Glueck (FDA)
	(Concurrent Sessions)		
	SESSION B: Process Validation and Automation	Learn general principles and approaches of Process Validation and the importance of ensuring control in the manufacturing process to produce consistent, quality products for patients. This presentation aligns process validation activities with a product lifecycle concept and existing FDA guidance documents for industry. There will be an industry/FDA panel discussion on the challenges facing our industry as they relate to automation and equipment validation.	*Presenter/Panelist* • Neda Hamandi (FDA) *Moderator* • Jennifer Del Valle Ortiz (FDA) *Panelists* • Iván Martínez (Leiters) • Cindy Mitman (Hikma Pharmaceuticals) • Tara Gooen Bizjak (FDA)
1:45-2:00 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.	*Moderator* • Alissa Gold (FDA) *Panelists* • Huascar Batista (FDA) • Ian Deveau (FDA) • Meghan Murphy (FDA) • Kathleen Anderson (FDA) • Gail Bormel (FDA) • Gabrielle Cosel (FDA) • Alonza Cruse (FDA) • Edisa Gozun (FDA) • Hidee Molina (FDA) • Jill Hammond (FDA)
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.	*Moderator* • Gabrielle Cosel (FDA) *Panelists* • David Glasser (American Academy of Ophthalmology) • Meghan Murphy (FDA) • April Yoo (Vizient, Inc.) • Joe Bagan (STAQ Pharma) • Kimberly Kieffer (AnazaoHealth Corporation) • Michael Evans (Geisinger)
4:30-4:45 PM ET	Closing Remarks		• Gail Bormel (FDA)