

Compounding Quality Center of Excellence 2022 Virtual Conference
The Shared Pursuit of Compounding Excellence
 September 6-8, 2022

PRE-CONFERENCE: TUESDAY, SEPTEMBER 6, 2022

Time	Session	Description
2:00 – 5:00 p.m. ET	Outsourcing Facility Nuts and Bolts: Reporting, Registration, and Other Topics	FDA will present an overview of logistical elements, including product reporting, registration, pre-inspection meeting requests, inspections, and posting to the bulk nomination and general compounding dockets.

DAY ONE: WEDNESDAY, SEPTEMBER 7, 2022

Time	Session	Description
11:00 – 11:15 a.m. ET	Opening Plenary Part 1 – Welcome Remarks	
11:15 a.m. – 12:15 p.m. ET	Opening Plenary Part 2 – Aligning on Compounding Excellence: Understanding Its Meaning Across the Sector	Panel discussion of what compounding ‘excellence’ means to a diverse group of stakeholders.
12:15 – 12:45 p.m. ET	Break	
12:45 – 1:45 p.m. ET	Session A: Visual Inspection	Presentation on visual inspection practices and related Current Good Manufacturing Practice (CGMP) regulations, including examples of FDA Form 483 observations and potential responses.
	OR (Concurrent Sessions)	
	Session B: Container Closure Systems	Presentation on qualifying container closure systems for intended use.
1:45 – 2:00 p.m. ET	Break	
2:00 – 3:00 p.m. ET	Roundtable Discussion: Stakeholder Perspectives on Areas of Need for Outsourcing Facility Products	Panel discussion with external stakeholders to discuss the areas of need for drug products compounded by outsourcing facilities, including

		FDA-sponsored research on stakeholder perspectives.
3:00 – 3:30 p.m. ET	<i>Break</i>	
3:30 – 4:30 p.m. ET	Coffee Break: Virtual Café	<p>Moderated breakout rooms focused on different topics:</p> <ol style="list-style-type: none"> 1. Understanding FDA Form 483 Process and Timeline 2. Product Reporting, Registration, and Other Requirements 3. Quality Risk Management 4. Automation

DAY TWO: THURSDAY, SEPTEMBER 8, 2022

Time	Session	Description
10:00 – 11:00 a.m. ET	FDA Hot Topics	Panel discussion on current Agency topics of interest to outsourcing facilities.
11:00 – 11:15 a.m. ET	Break	
11:15 a.m. – 12:00 p.m. ET	Hospital Health System Guidance Presentation	Presentation on revised draft compounding guidance for health systems.
12:00 – 12:30 p.m. ET	Break	
12:30 – 1:30 p.m. ET	Roundtable Discussion — 503B Hospital Panel: How are Outsourcing Facilities Evaluated by Prospective Customers?	Panel discussion on hospital and health system approaches to evaluating and selecting outsourcing facility partners.
1:30 – 2:00 p.m. ET	Break	
2:00 – 2:45 p.m. ET	Building Connections: Perspectives from the Field	Case study presentation highlighting stakeholder collaboration to address patient needs
2:45 – 3:15 p.m. ET	Break	
3:15 – 4:15 p.m. ET	Closing Plenary Part 1 — Building Connections: Advancing Our Shared Pursuit of Compounding Quality	Moderated panel on building cross-sector connections to advance compounding excellence.
4:15 – 4:30 p.m. ET	Closing Plenary Part 2 — Closing Remarks	